

US3432497 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:39:14

All time stamps listed in this document are displayed in GMT

US3432497

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Participant ID

US3432497

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

US3432497

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 25 Apr 2021 11:23:40

Generated On: 09 Jun 2021 17:39:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 25 Apr 2021 11:23:40

Generated On: 09 Jun 2021 17:39:14

Date of Informed Consent (<i>dd MMM yyyy</i>)	28 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 type="radio"/>
	Amendment 3 <input checked="" 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 checked="" type="radio"/>
	No <input type="radio"/>
If Yes, previous participant number	US3432324
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 03:04:26

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 25 Apr 2021 11:23:40

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Condition	DEPRESSION
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)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Apr 2021 11:23:40

Generated On: 09 Jun 2021 17:39:14

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 25 Apr 2021 11:23:40

Generated On: 09 Jun 2021 17:39:14

Condition	CHRONIC LEG CRAMPS
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 25 Apr 2021 11:23:40

Generated On: 09 Jun 2021 17:39:14

Condition	NON-PRURITIC EXCORIATION (LEFT WRIST)
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	07:21 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 07:21
Height (<i>xxx.x</i>)	159 cm
Weight (<i>xxx.x</i>)	047.2 kg
BMI (<i>xxx.x</i>)	18.67015 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 03:04:26

Generated On: 09 Jun 2021 17:39:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Date of assessment (*dd MMM yyyy*) 27 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*) UN UNK 2005

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

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 03:04:26

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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 03:04:27

Generated On: 09 Jun 2021 17:39:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

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

What was the participant's randomization number? 190804

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 03:04:27

Generated On: 09 Jun 2021 17:39:14

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	07:21 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 07:21
Temperature (xxx.x)	98.0 F
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	091 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 03:04:27

Generated On: 09 Jun 2021 17:39:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	09:02 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 09:02
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	IR
Pulse (xxx)	072 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)	087 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 03:04:27

Generated On: 09 Jun 2021 17:39:14

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 08:28 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 08:28

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 SEP 2020

Collection time (00:00-23:59)

07:30 (24 HR)

Collection date and time (derived)

14 SEP 2020 07:30

US3432497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:37	14 SEP 2020 07:37
Nasopharyngeal Swab 2	No		

US3432497

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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

97.3 °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 09:04

PC Open Date & Time

14 SEP 2020 08:48

PC Close Date & Time

14 SEP 2020 11:18

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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

98.1 °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 19:00
PC Open Date & Time	14 SEP 2020 12:13
PC Close Date & Time	15 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

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):

PC Time Stamp 15 SEP 2020 18:58

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

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

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

16 SEP 2020 19:02

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

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

98.1 °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 SEP 2020 18:57

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 18:33

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

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

97.5 °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

19 SEP 2020 19:04

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

20 SEP 2020 18:51

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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

14 SEP 2020 09:05

PC Open Date & Time

14 SEP 2020 08:48

PC Close Date & Time

14 SEP 2020 11:18

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 19:01

PC Open Date & Time

14 SEP 2020 12:13

PC Close Date & Time

15 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 18:59

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 19:03

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

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

17 SEP 2020 18:58

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

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

18 SEP 2020 18:33

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

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

19 SEP 2020 19:04

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 18:51

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 09:05
PC Open Date & Time	14 SEP 2020 08:48
PC Close Date & Time	14 SEP 2020 11:18

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 19:02
PC Open Date & Time	14 SEP 2020 12:13
PC Close Date & Time	15 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

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 ☒

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 19:00
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

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 2066

EAB) (1725)

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 19:03
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

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 2066

EAB) (1725)

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

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 2066

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 18:34
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

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 ☒

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 19:05
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

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

56 of 2066

EAB) (1725)

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 18:52
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3432497

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3432497

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3432497

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3432497

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

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

Visit date (dd MMM yyyy)	14 OCT 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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US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	16:10 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 16:10
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

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)	14 OCT 2020
Time of assessment (00:00-23:59)	17:21 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 17:21
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3432497

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3432497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 16:50 (24 HR)

Treatment Date and Time (derived) 14 OCT 2020 16:50

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

US3432497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

16:35 (24 HR)

Collection date and time (derived)

14 OCT 2020 16:35

US3432497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Collection date (dd MMM yyyy)			14 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:40	14 OCT 2020 16:40
Nasopharyngeal Swab 2	No		

US3432497

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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

14 OCT 2020 17:27

PC Open Date & Time

14 OCT 2020 17:10

PC Close Date & Time

14 OCT 2020 19:40

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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 96.9 °F

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

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

PC Time Stamp	14 OCT 2020 20:40
PC Open Date & Time	14 OCT 2020 20:35
PC Close Date & Time	15 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

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 100.2 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 15 OCT 2020 18:03

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

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

99.1 °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 OCT 2020 18:42

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

17 OCT 2020 19:43

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

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

98.5 °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

18 OCT 2020 19:03

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 20:26

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 18:56

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 17:27

PC Open Date & Time

14 OCT 2020 17:10

PC Close Date & Time

14 OCT 2020 19:40

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 20:40

PC Open Date & Time

14 OCT 2020 20:35

PC Close Date & Time

15 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 18:04

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 18:42

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

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

17 OCT 2020 19:43

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

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

18 OCT 2020 19:03

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

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

19 OCT 2020 20:27

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 18:57

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 17:27
PC Open Date & Time	14 OCT 2020 17:10
PC Close Date & Time	14 OCT 2020 19:40

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 20:41
PC Open Date & Time	14 OCT 2020 20:35
PC Close Date & Time	15 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 18:05
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

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

94 of 2066

EAB) (1725)

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 18:43
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

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

96 of 2066

EAB) (1725)

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 19:43
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

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

98 of 2066

EAB) (1725)

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 19:04
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

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

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EAB) (1725)

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 20:27
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

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

102 of 2066

EAB) (1725)

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 18:57
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3432497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3432497

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3432497

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3432497

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 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

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	9:15 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 9:15
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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432497

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

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.

US3432497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 NOV 2020

Collection time (00:00-23:59)

9:49 (24 HR)

Collection date and time (derived)

12 NOV 2020 9:49

US3432497

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:04:27

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432497

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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	17 NOV 2020 19:01:58
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 68
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 NOV 2020 15:28:44
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 75
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	27 NOV 2020 17:06:45
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 82

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

02 DEC 2020 07:24:40

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 89
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	11 DEC 2020 14:15:20
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 96
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	16 DEC 2020 08:14:03
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

23 DEC 2020 07:50:41

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☒

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

01 JAN 2021 12:02:34

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 20:54:37
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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	15 JAN 2021 12:07:09
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☒

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 JAN 2021 08:45:20

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☒

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

27 JAN 2021 09:09:58

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☒

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 13:43:52

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 FEB 2021 05:33:20

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 08:12:34

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 12:00:16
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

03 MAR 2021 09:28:02

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

11 MAR 2021 09:22:01

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 07:43:36
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

24 MAR 2021 05:53:48

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☒

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

31 MAR 2021 07:13:26

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 <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	07 APR 2021 07:03:23
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 <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	18 APR 2021 11:59:49
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 <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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 <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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	10 OCT 2021 23:59
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US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	17 OCT 2021 23:59
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US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 425

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

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

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

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

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

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	14 NOV 2021 23:59
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US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

Patient Cloud Open Date & Time	24 NOV 2021 00:01
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Patient Cloud Close Date & Time	28 NOV 2021 23:59
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US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 <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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	10 APR 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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°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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	05 JUN 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	03 JUL 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 <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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐ 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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 AUG 2022 00:01
Patient Cloud Close Date & Time	28 AUG 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 <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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 <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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	16 OCT 2022 23:59
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US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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="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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

Date and time of submission	
Patient Cloud Open Date & Time	26 OCT 2022 00:01
Patient Cloud Close Date & Time	30 OCT 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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

Date and time of submission	
Patient Cloud Open Date & Time	16 NOV 2022 00:01
Patient Cloud Close Date & Time	20 NOV 2022 23:59

US3432497

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:39:14

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		03 MAR 2021 09:28:20

US3432497

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3432497

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432497

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3432497

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432497

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3432497

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432497

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3432497

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432497

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Apr 2021 11:23:41

Generated On: 09 Jun 2021 17:39:14

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

Visit date (dd MMM yyyy)	05 APR 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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US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Apr 2021 11:23:41

Generated On: 09 Jun 2021 17:39:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 APR 2021
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	05 APR 2021 11:45
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	080 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	015 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	073 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432497

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Apr 2021 11:23:41

Generated On: 09 Jun 2021 17:39:14

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.

US3432497

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Apr 2021 11:23:41

Generated On: 09 Jun 2021 17:39:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 APR 2021

Collection time (00:00-23:59)

12:00 (24 HR)

Collection date and time (derived)

05 APR 2021 12:00

US3432497

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 11:23:41

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432497

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Date of Contact	5 OCT 2020
Time of Contact	12:45
Date and Time of Contact (derived)	5 OCT 2020 12:45
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>

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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	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 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"/>

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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"/>

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

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"/>

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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	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 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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"/>

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

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 05 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	03 OCT 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 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 05 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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 05 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

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 05 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	4 OCT 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 type="radio"/>
	Moderate	<input checked="" 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 05 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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 05 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

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

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	5 OCT 2020
------	------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	37.5 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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EAB) (1725)

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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 05 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 05 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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	06 OCT 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	97.8 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 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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EAB) (1725)

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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"/>

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

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"/>

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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	07 OCT 2020
------	-------------

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

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

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

Temperature	97.2 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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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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 05 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

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"/>

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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	08 OCT 2020
------	-------------

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

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

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

Temperature	96.5 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 05 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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 05 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

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"/>

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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	09 OCT 2020
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	98.0 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 05 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

	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 05 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

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"/>

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Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Date of Visit	5 OCT 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	5 OCT 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

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:39:14

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 25 Apr 2021 11:23:40

Generated On: 09 Jun 2021 17:39:14

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	07 OCT 2020
Day 5	Yes	08 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)	

US3432497

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

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

Visit date (dd MMM yyyy)	05 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	SICKD1
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US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 OCT 2020
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 12:50
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	37.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 OCT 2020

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

US3432497

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 21:13:33

Generated On: 09 Jun 2021 17:39:14

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

05 OCT 2020

US3432497

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

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

Visit date (dd MMM yyyy)	25 JAN 2021
--------------------------	-------------

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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US3432497

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

Form: Unblinding

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Date of updated informed consent (dd MMM yyyy) 25 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 25 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3432497

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 21:13:33

Generated On: 09 Jun 2021 17:39:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 JAN 2021

Collection time (00:00-23:59)

13:27 (24 HR)

Collection date and time (derived)

25 JAN 2021 13:27

US3432497

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 JAN 2021

Collection time (00:00 - 23:59)

13:30

Collection Date and Time (derived)

25 JAN 2021 13:30

US3432497

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 25 Apr 2021 11:23:39

Generated On: 09 Jun 2021 17:39:14

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

AEID	USA-US078-2021-MRNA-1273-P30 1000021
Adverse event	BREAST CANCER (L BREAST)
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)	12 APR 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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

PARTICIPANT REPORTS
RECENT DIAGNOSIS OF
BREAST CANCER. IS GOING
FOR FOLLOWING UP TESTING
AND GRADING IN THE WEEKS
TO COME. WILL UPDATE WITH
MORE INFORMATION AS THE
CARE TEAM MOVES FORWARD
WITH TREATMENT PLANS.
BIOPSY ON 08APR2021
INDICATED INVASIVE DUCTAL
CARCINOMA

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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 03:04:26

Generated On: 09 Jun 2021 17:39:14

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 11:23:39

Generated On: 09 Jun 2021 17:39:14

Name of Medication LEXAPRO

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 40

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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US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 11:23:39

Generated On: 09 Jun 2021 17:39:14

	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"/>

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:23:39

Generated On: 09 Jun 2021 17:39:14

Name of Medication VITAMIN B12

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:23:39

Generated On: 09 Jun 2021 17:39:14

	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 2019	
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"/>

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 11:23:39

Generated On: 09 Jun 2021 17:39:14

Name of Medication MAGNESIUM

Prophylaxis Yes ☐
No ☒

Indication LEG CRAMPS

Dose per administration 250

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 11:23:39

Generated On: 09 Jun 2021 17:39:14

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:23:39

Generated On: 09 Jun 2021 17:39:14

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication FEVER

Dose per administration 400

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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US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:23:39

Generated On: 09 Jun 2021 17:39:14

	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)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 OCT 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"/>

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 11:23:39

Generated On: 09 Jun 2021 17:39:14

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify UNIT

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 (5)

Data signed: (b) (4) 25 Apr 2021 11:23:39

Generated On: 09 Jun 2021 17:39:14

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		5 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		5 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Apr 2021 11:23:39

Generated On: 09 Jun 2021 17:39:14

Name of Medication HYDROCORTISONE (1%)

Prophylaxis Yes ☐
No ☒

Indication NON-PRURITIC EXCORIATION
(LEFT WRIST)

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Apr 2021 11:23:39

Generated On: 09 Jun 2021 17:39:14

	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)	UN UNK 2018	
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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3432497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 25 Apr 2021 11:23:40

Generated On: 09 Jun 2021 17:39:14

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3432497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 30 Apr 2021 18:52:05

Generated On: 09 Jun 2021 17:39:14

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 MAR 2021	MAMMOGRAM	Diagnostic	
08 APR 2021	BIOPSY	Diagnostic	

US3432497

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:39:14

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

US3432497

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:39:14

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 ☐

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 18:52:05

Generated On: 09 Jun 2021 17:39:14

SAEID	USA-US078-2021-MRNA-1273-P301000021
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	2

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 18:52:05

Generated On: 09 Jun 2021 17:39:14

SAEID	USA-US078-2021-MRNA-1273-P301000021
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	2
Date of submission (Pre-filled from custom function)	21/APR/2021 13:03
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

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 18:52:05

Generated On: 09 Jun 2021 17:39:14

SAEID	USA-US078-2021-MRNA-1273-P301000021
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	2
Date of submission (Pre-filled from custom function)	30/APR/2021 14:12
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

US3432497 (Prod: Brigham and Womens Hospital)

US3432497

Form: Participant Creation

Generated On: 09 Jun 2021 17:39:14

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:06:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'US3432497'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 11:39:51

US3432497

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:08:53
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:53:58

US3432497

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:53
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	23 Apr 2021 19:59:44
User entered '14 Sep 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	23 Apr 2021 19:59:44
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	23 Apr 2021 14:25:05
DataPoint Un-verified.	RWS_ENDPOINT ENDPOINT (b) (4)	23 Apr 2021 14:25:05
Signature has been broken.	RWS_ENDPOINT ENDPOINT (b) (4)	23 Apr 2021 14:25:05
User entered '27 AUG 2020' reason for change: Data Entry Error	RWS_ENDPOINT ENDPOINT (b) (4)	23 Apr 2021 14:25:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:23:49
User entered '14 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 11:39:52

US3432497

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

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 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:24
User entered 'Clinic (Clinic)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:53:58

US3432497

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'SCRN'	System	14 Sep 2020 11:53:58

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:47
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 11:39:54

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:47
User entered '67'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:14

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'YEARS'	System	14 Sep 2020 11:54:14

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered '67'	System	14 Sep 2020 11:54:35

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:47
User entered 'Female (F)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:14

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:47
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:14

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:47
User entered 'I'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:14

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:47
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:14

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:47
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:14

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:47
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:14

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:47
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:14

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:47
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:14

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:47
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:14

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:47
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:14

US3432497

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:14

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:47
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:14

US3432497

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:14

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:21
User closed query 'As discussed please update date of ICF to 28Aug20, add note in source' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 11:41:43
Query 'As discussed please update date of ICF to 28Aug20, add note in source' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Oct 2020 15:46:57
User entered '28 Aug 2020' reason for change: Per Query Resolution	Monica Feeley (b) (4)	20 Oct 2020 15:46:53
User opened query 'As discussed please update date of ICF to 28Aug20, add note in source' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 21:52:45
User entered '14 Sep 2020'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:35

US3432497

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'Aug 2020'	System	20 Oct 2020 15:46:53
User entered 'Sep 2020'	System	14 Sep 2020 11:54:35

US3432497

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered '2020'	System	14 Sep 2020 11:54:35

US3432497

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:14

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:21
User entered 'Amendment 3 (3)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:35

US3432497

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:21
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:35

US3432497

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:14

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:21
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:35

US3432497

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:21
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:35

US3432497

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:21
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:54:35

US3432497

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:02:47
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Un-verified.	RWS_ENDPOINT ENDPOINT (b) (4)	23 Apr 2021 14:25:05
User entered 'US3432324' reason for change: Data Entry Error	RWS_ENDPOINT ENDPOINT (b) (4)	23 Apr 2021 14:25:05
Query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' canceled (Site from System).	(b) (4), (b) (6)	21 Apr 2021 16:18:31
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 05:39:29
Comment added 'Needs unlock'.	Julia Klopfer (b) (4)	09 Apr 2021 17:24:25
Comment added 'Hello please help us by unlocking this so it can be entered'.	Julia Klopfer (b) (4)	09 Apr 2021 17:24:15
Comment added 'Please unlock this field so we can enter the value'.	Julia Klopfer (b) (4)	07 Apr 2021 23:36:35
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:50:48
Comment added 'We are unable to enter previous PTID (US3432324). Please unlock field so this query can be resolved as requested for database lock.'	Jessica Cauley (b) (4)	14 Jan 2021 22:06:03
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:21
Comment added 'The PTID is US3432324. Unfortunately, the field is closed. Where can I put this information?'.	(b) (4), (b) (6)	16 Sep 2020 13:19:39
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	14 Sep 2020 11:54:35
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 11:39:52

US3432497

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'I'	System	14 Sep 2020 11:55:21

US3432497

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:28
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:55:21

US3432497

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:39:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:30
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 21:24:19

US3432497

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:12
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 21:25:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 21:25:48
Data point term sent to Coder	System	14 Sep 2020 21:25:14
User entered 'Depression'	Xhoi Mitre (b) (4)	14 Sep 2020 21:24:41

US3432497

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:12
User entered 'UN UNK 1990'	Xhoi Mitre (b) (4)	14 Sep 2020 21:24:41

US3432497

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:12
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 21:24:41

US3432497

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:12
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 21:24:41

US3432497

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:12
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 21:24:41

US3432497

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:12
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 21:24:41

US3432497

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'Jan 1990'	System	14 Sep 2020 21:24:41

US3432497

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered '1990'	System	14 Sep 2020 21:24:41

US3432497

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered empty.	System	14 Sep 2020 21:24:41

US3432497

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered empty.	System	14 Sep 2020 21:24:41

US3432497

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:38:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 17:17:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 17:17:05
Data point term sent to Coder	System	04 Dec 2020 17:15:55
User entered 'Post-menopausal'	Alexander Mills (b) (4)	04 Dec 2020 17:15:24

US3432497

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:38:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'un UNK 2005'	Alexander Mills (b) (4)	04 Dec 2020 17:15:24

US3432497

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:38:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '0'	Alexander Mills (b) (4)	04 Dec 2020 17:15:24

US3432497

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:38:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Yes (Y)'	Alexander Mills (b) (4)	04 Dec 2020 17:15:24

US3432497

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:38:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered empty.	Alexander Mills (b) (4)	04 Dec 2020 17:15:24

US3432497

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:38:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '0'	Alexander Mills (b) (4)	04 Dec 2020 17:15:24

US3432497

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'Jan 2005'	System	04 Dec 2020 17:15:24

US3432497

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered '2005'	System	04 Dec 2020 17:15:24

US3432497

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered empty.	System	04 Dec 2020 17:15:24

US3432497

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered empty.	System	04 Dec 2020 17:15:24

US3432497

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:38:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Leg cramps - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 19:19:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 19:19:49
Data point term sent to Coder	System	07 Dec 2020 14:22:28
User entered 'Chronic leg cramps'	(b) (4), (b) (6)	07 Dec 2020 14:22:10

US3432497

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:38:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'UN UNK 1980'	(b) (4), (b) (6)	07 Dec 2020 14:22:10

US3432497

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:38:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 14:22:10

US3432497

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:38:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 14:22:10

US3432497

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:38:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 14:22:10

US3432497

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:38:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 14:22:10

US3432497

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'Jan 1980'	System	07 Dec 2020 14:22:10

US3432497

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered '1980'	System	07 Dec 2020 14:22:10

US3432497

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered empty.	System	07 Dec 2020 14:22:10

US3432497

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered empty.	System	07 Dec 2020 14:22:10

US3432497

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin abrasion, LLT: Excoriation - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 19:31:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 19:31:55
Data point term sent to Coder	System	05 Apr 2021 16:52:11
User entered 'Non-pruritic excoriation (left wrist)'	Bethany Evans (b) (4)	05 Apr 2021 16:52:02

US3432497

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:30
User entered 'UN UNK 2018'	Bethany Evans (b) (4)	05 Apr 2021 16:52:02

US3432497

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:30
User entered '0'	Bethany Evans (b) (4)	05 Apr 2021 16:52:02

US3432497

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:30
User entered 'Yes (Y)'	Bethany Evans (b) (4)	05 Apr 2021 16:52:02

US3432497

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:30
User entered empty.	Bethany Evans (b) (4)	05 Apr 2021 16:52:02

US3432497

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:30
User entered '0'	Bethany Evans (b) (4)	05 Apr 2021 16:52:02

US3432497

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'Jan 2018'	System	05 Apr 2021 16:52:02

US3432497

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered '2018'	System	05 Apr 2021 16:52:02

US3432497

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered empty.	System	05 Apr 2021 16:52:02

US3432497

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered empty.	System	05 Apr 2021 16:52:02

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:15
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	23 Apr 2021 19:59:44
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	23 Apr 2021 19:59:44
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	23 Apr 2021 14:25:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:15
User entered '14 Sep 2020'	Xhoi Mitre (b) (4)	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:15
User entered '07:21'	Xhoi Mitre (b) (4)	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered '14 Sep 2020 07:21'	System	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:15
User entered '159' cm	Xhoi Mitre (b) (4)	14 Sep 2020 23:12:26
DataPoint set to visible.	(b) (4) System	14 Sep 2020 11:55:21

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:15
User entered '047.2' kg	Xhoi Mitre (b) (4)	14 Sep 2020 23:12:26
DataPoint set to visible.	(b) (4) System	14 Sep 2020 11:55:21

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered '18.67015'	System	14 Sep 2020 23:12:26
DataPoint set to visible.	System	14 Sep 2020 11:55:21

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'kg/m2'	System	14 Sep 2020 23:12:26
DataPoint set to visible.	System	14 Sep 2020 11:55:21

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:15
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:15
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:15
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:15
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'bpm'	System	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:15
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'breaths/min'	System	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:15
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'mmHg'	System	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:15
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'mmHg'	System	14 Sep 2020 23:12:26

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34

US3432497

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34

US3432497

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:19
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:56:23

US3432497

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:19
User entered '14 Sep 2020'	Xhoi Mitre (b) (4)	14 Sep 2020 11:56:23

US3432497

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:39:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:50:45
User closed query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	23 Nov 2020 20:32:27
User entered '27 Aug 2020' reason for change: Per Query Resolution	Alexander Mills (b) (4)	23 Nov 2020 20:32:27
User opened query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	20 Oct 2020 15:46:53
User entered '14 Sep 2020'	Xhoi Mitre (b) (4)	14 Sep 2020 11:56:13

US3432497

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:39:14

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:00:30
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:56:13

US3432497

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:39:14

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User closed query 'Per CDM RQ: Response noted, however per Sponsor request, supporting documentation for Post-Menopausal should be entered in MH. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:39:18
Query 'Per CDM RQ: Response noted, however per Sponsor request, supporting documentation for Post-Menopausal should be entered in MH. Thank you.' answered with 'Updated' (Site from DM).	Alexander Mills (b) (4)	04 Dec 2020 17:16:30
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:00:32
User opened query 'Per CDM RQ: Response noted, however per Sponsor request, supporting documentation for Post-Menopausal should be entered in MH. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:16:44
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:16:44
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'not a medical condition? normal aging process' (Site from DM).	Monica Feeley (b) (4)	08 Oct 2020 16:20:54
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:24:49
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:56:13

US3432497

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:39:14

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:00:35
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 11:56:13

US3432497

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:00:35
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 11:56:13

US3432497

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:39:14

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:00:35
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:56:13

US3432497

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:00:35
User entered 'UN UNK 2005'	Xhoi Mitre (b) (4)	14 Sep 2020 11:56:13

US3432497

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:39:14

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:00:35
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:56:13

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

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)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

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)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

[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)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

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Folder: Screening

Form: Risk of Exposure

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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)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

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)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

[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)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

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)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

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Folder: Screening

Form: Risk of Exposure

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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)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

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)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

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)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

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)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered 'I'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:05
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 11:57:01

US3432497

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:02
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:59:28

US3432497

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:02
User entered '14 Sep 2020'	Xhoi Mitre (b) (4)	14 Sep 2020 11:59:28

US3432497

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:02
User entered 'Clinic (Clinic)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:59:28

US3432497

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'VISIT1'	System	14 Sep 2020 11:59:28

US3432497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:08
User entered '14 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 11:44:37

US3432497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:14

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:08
User entered '190804'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 11:44:37

US3432497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:08
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 11:44:37

US3432497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:14

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)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:08
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:59:45

US3432497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:14

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)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:08
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:59:45

US3432497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:08
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:59:45

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:14

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:08
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:59:45

US3432497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:14

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:08
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:59:45

US3432497

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:14

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:08
User closed query 'please complete' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 11:44:51
Query 'please complete' answered by data change (Site from CRA).	System	20 Oct 2020 15:46:33
User entered 'No (N)'	Monica Feeley (b) (4)	20 Oct 2020 15:46:33
User opened query 'please complete' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 21:57:46
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:07:43
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:07:42

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User accepted default value 'Pre-Dose (PREDOSE)'	Xhoi Mitre (b) (4) (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '14 Sep 2020'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '07:21'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered '14 Sep 2020 07:21'	System	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '98.0' F	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered 'Oral (Oral)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '087'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'bpm'	System	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '12'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'breaths/min'	System	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '144'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'mmHg'	System	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '091'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'mmHg'	System	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User accepted default value 'Post-Dose (POSTDOSE)'	Xhoi Mitre (b) (4) (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '14 Sep 2020'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '09:02'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered '14 Sep 2020 09:02'	System	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '97.3' F	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered 'Other (Other)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered 'IR'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '072'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'bpm'	System	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '14'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'breaths/min'	System	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '128'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'mmHg'	System	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:49
User entered '087'	Xhoi Mitre (b) (4)	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'mmHg'	System	14 Sep 2020 23:14:46

US3432497

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:55
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 11:59:48

US3432497

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:01:55
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 11:59:48

US3432497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:16
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 12:57:23

US3432497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:16
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 12:57:23

US3432497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

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)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:16
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 12:57:23

US3432497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 12:57:23

US3432497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:16
User entered '14 Sep 2020'	Xhoi Mitre (b) (4)	14 Sep 2020 12:57:23

US3432497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:16
User entered '08:28'	Xhoi Mitre (b) (4)	14 Sep 2020 12:57:23

US3432497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered '14 Sep 2020 08:28'	System	14 Sep 2020 12:57:23

US3432497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:16
User entered 'Left Arm (LEFT ARM)'	Xhoi Mitre (b) (4)	14 Sep 2020 12:57:23

US3432497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:16
User entered 'ONCE'	System	14 Sep 2020 12:57:23

US3432497

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 12:57:23

US3432497

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:22
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 14SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:31:00
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 14SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail ' answered with 'Got report back from PPD saying they received samples.' (Site from DM).	Jun Bai Park Chang (b) (4)	07 Oct 2020 14:56:02
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 14SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 02:58:51
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:15:06

US3432497

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:22
User entered '14 Sep 2020'	Xhoi Mitre (b) (4)	14 Sep 2020 23:15:06

US3432497

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:22
User entered '07:30'	Xhoi Mitre (b) (4)	14 Sep 2020 23:15:06

US3432497

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered '14 Sep 2020 07:30'	System	14 Sep 2020 23:15:06

US3432497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:39:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:27
User entered '14 Sep 2020'	Xhoi Mitre (b) (4)	14 Sep 2020 23:15:20

US3432497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Xhoi Mitre (b) (4) (b) (4)	14 Sep 2020 23:15:20

US3432497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:27
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:15:20

US3432497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:27
User entered '07:37'	Xhoi Mitre (b) (4)	14 Sep 2020 23:15:20

US3432497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered '14 Sep 2020 07:37'	System	14 Sep 2020 23:15:20

US3432497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Xhoi Mitre (b) (4) (b) (4)	14 Sep 2020 23:15:20

US3432497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:27
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:15:20

US3432497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:27
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 23:15:20

US3432497

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered empty.	System	14 Sep 2020 23:15:20

US3432497

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:30
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 22:10:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 22:10:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	15 Sep 2020 22:10:20
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 23:15:28
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	14 Sep 2020 23:15:28

US3432497

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered '1'	System	15 Sep 2020 22:10:20
User entered empty.	System	14 Sep 2020 23:15:28

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:03:55', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '26df7490-5af9-492d-8b43-b4bd466f8fa5' User entered 'Yes (Y)'	System	14 Sep 2020 13:04:29
	System	14 Sep 2020 13:04:29

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:04:15', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '26df7490-5af9-492d-8b43-b4bd466f8fa5' User entered '97.3'	System	14 Sep 2020 13:04:29
	System	14 Sep 2020 13:04:29

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:04:20', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '26df7490-5af9-492d-8b43-b4bd466f8fa5' User entered 'No (N)'	System	14 Sep 2020 13:04:29
	System	14 Sep 2020 13:04:29

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:04:27', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '26df7490-5af9-492d-8b43-b4bd466f8fa5' User entered '14 Sep 2020 09:04'	System	14 Sep 2020 13:04:29
	System	14 Sep 2020 13:04:29

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Sep 2020 08:48'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Sep 2020 11:18'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:00:11', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f65c4d7c-e36a-413c-8808-d3ff956a8b94' User entered 'Yes (Y)'	System	14 Sep 2020 23:00:58
	System	14 Sep 2020 23:00:58

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:00:39', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f65c4d7c-e36a-413c-8808-d3ff956a8b94' User entered '98.1'	System	14 Sep 2020 23:00:58
	System	14 Sep 2020 23:00:58

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:00:43', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f65c4d7c-e36a-413c-8808-d3ff956a8b94'	System	14 Sep 2020 23:00:58
User entered 'No (N)'	System	14 Sep 2020 23:00:58

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:00:53', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f65c4d7c-e36a-413c-8808-d3ff956a8b94' User entered '14 Sep 2020 19:00'	System	14 Sep 2020 23:00:58
	System	14 Sep 2020 23:00:58

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Sep 2020 12:13'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 2'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T18:57:47', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'b2e5b4b9-b387-4a35-a3cc-9b3f1ffe695f' User entered 'No (N)'	System	15 Sep 2020 22:58:05
	System	15 Sep 2020 22:58:05

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T18:57:51', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'b2e5b4b9-b387-4a35-a3cc-9b3f1ffe695f' User entered 'No (N)'	System	15 Sep 2020 22:58:05
	System	15 Sep 2020 22:58:05

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T18:58:02', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'b2e5b4b9-b387-4a35-a3cc-9b3f1ffe695f' User entered '15 Sep 2020 18:58'	System	15 Sep 2020 22:58:05
	System	15 Sep 2020 22:58:05

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 3'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:02:27', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'bf90e735-1afd-4ec1-947f-f0b1592ef2fa' User entered 'Yes (Y)'	System	17 Sep 2020 00:34:09
	System	17 Sep 2020 00:34:09

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:02:34', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'bf90e735-1afd-4ec1-947f-f0b1592ef2fa' User entered '98.3'	System	17 Sep 2020 00:34:09
	System	17 Sep 2020 00:34:09

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:02:39', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'bf90e735-1afd-4ec1-947f-f0b1592ef2fa'	System	17 Sep 2020 00:34:09
User entered 'No (N)'	System	17 Sep 2020 00:34:09

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:02:48', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'bf90e735-1afd-4ec1-947f-f0b1592ef2fa' User entered '16 Sep 2020 19:02'	System	17 Sep 2020 00:34:09
	System	17 Sep 2020 00:34:09

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 4'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:56:28', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '39d70d7b-624e-41e7-aecd-1c66e60fa452' User entered 'Yes (Y)'	System	17 Sep 2020 22:57:27
	System	17 Sep 2020 22:57:27

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:57:09', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '39d70d7b-624e-41e7-aecd-1c66e60fa452' User entered '98.1'	System	17 Sep 2020 22:57:27
	System	17 Sep 2020 22:57:27

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:57:14', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '39d70d7b-624e-41e7-aecd-1c66e60fa452'	System	17 Sep 2020 22:57:27
User entered 'No (N)'	System	17 Sep 2020 22:57:27

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:57:23', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '39d70d7b-624e-41e7-aecd-1c66e60fa452' User entered '17 Sep 2020 18:57'	System	17 Sep 2020 22:57:27
	System	17 Sep 2020 22:57:27

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 5'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:33:01', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9f7644ae-4132-46fe-9ee5-b245c0d7104a' User entered 'Yes (Y)'	System	18 Sep 2020 22:33:27
	System	18 Sep 2020 22:33:27

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:33:09', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9f7644ae-4132-46fe-9ee5-b245c0d7104a' User entered '96.9'	System	18 Sep 2020 22:33:27
	System	18 Sep 2020 22:33:27

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:33:15', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9f7644ae-4132-46fe-9ee5-b245c0d7104a' User entered 'No (N)'	System	18 Sep 2020 22:33:27
	System	18 Sep 2020 22:33:27

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:33:22', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9f7644ae-4132-46fe-9ee5-b245c0d7104a' User entered '18 Sep 2020 18:33'	System	18 Sep 2020 22:33:27
	System	18 Sep 2020 22:33:27

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 6'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:03:03', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '65f18a54-e191-4a67-aca0-47518333709c' User entered 'Yes (Y)'	System	19 Sep 2020 23:04:15
	System	19 Sep 2020 23:04:15

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:03', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '65f18a54-e191-4a67-aca0-47518333709c' User entered '97.5'	System	19 Sep 2020 23:04:15
	System	19 Sep 2020 23:04:15

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:07', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '65f18a54-e191-4a67-aca0-47518333709c' User entered 'No (N)'	System	19 Sep 2020 23:04:15
	System	19 Sep 2020 23:04:15

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:11', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '65f18a54-e191-4a67-aca0-47518333709c' User entered '19 Sep 2020 19:04'	System	19 Sep 2020 23:04:15
	System	19 Sep 2020 23:04:15

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 7'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:50:55', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '86b14814-a578-4994-9ba4-405bf26cbf9f' User entered 'Yes (Y)'	System	20 Sep 2020 22:51:14
	System	20 Sep 2020 22:51:14

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:02', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '86b14814-a578-4994-9ba4-405bf26cbf9f' User entered '97.3'	System	20 Sep 2020 22:51:14
	System	20 Sep 2020 22:51:14

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:07', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '86b14814-a578-4994-9ba4-405bf26cbf9f' User entered 'No (N)'	System	20 Sep 2020 22:51:14
	System	20 Sep 2020 22:51:14

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:12', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '86b14814-a578-4994-9ba4-405bf26cbf9f' User entered '20 Sep 2020 18:51'	System	20 Sep 2020 22:51:14
	System	20 Sep 2020 22:51:14

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:04:40', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '48871657-c48c-4b57-973f-42439bc47474' User entered 'None (1)'	System	14 Sep 2020 13:05:11
	System	14 Sep 2020 13:05:11

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:04:46', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '48871657-c48c-4b57-973f-42439bc47474' User entered 'No (N)'	System	14 Sep 2020 13:05:11
	System	14 Sep 2020 13:05:11

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:04:51', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '48871657-c48c-4b57-973f-42439bc47474' User entered 'No (N)'	System	14 Sep 2020 13:05:11
	System	14 Sep 2020 13:05:11

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:04:59', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '48871657-c48c-4b57-973f-42439bc47474' User entered 'None (1)'	System	14 Sep 2020 13:05:11
	System	14 Sep 2020 13:05:11

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:05:08', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '48871657-c48c-4b57-973f-42439bc47474' User entered '14 Sep 2020 09:05'	System	14 Sep 2020 13:05:11
	System	14 Sep 2020 13:05:11

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Sep 2020 08:48'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Sep 2020 11:18'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:01:09', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '5fd31af5-1d92-4f6b-96fb-2c7b62bad229'	System	14 Sep 2020 23:02:03
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 23:02:03

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:01:33', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '5fd31af5-1d92-4f6b-96fb-2c7b62bad229' User entered 'No (N)'	System	14 Sep 2020 23:02:03
	System	14 Sep 2020 23:02:03

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:01:39', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '5fd31af5-1d92-4f6b-96fb-2c7b62bad229' User entered 'No (N)'	System	14 Sep 2020 23:02:03
	System	14 Sep 2020 23:02:03

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:01:49', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '5fd31af5-1d92-4f6b-96fb-2c7b62bad229'	System	14 Sep 2020 23:02:03
User entered 'None (1)'	System	14 Sep 2020 23:02:03

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:01:58', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '5fd31af5-1d92-4f6b-96fb-2c7b62bad229' User entered '14 Sep 2020 19:01'	System	14 Sep 2020 23:02:03
	System	14 Sep 2020 23:02:03

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Sep 2020 12:13'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 2'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T18:58:13', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'a3c057b4-90af-4c5e-b204-8c6f7a5583ab'	System	15 Sep 2020 22:59:38
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 22:59:38

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T18:59:06', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'a3c057b4-90af-4c5e-b204-8c6f7a5583ab' User entered 'No (N)'	System	15 Sep 2020 22:59:38
	System	15 Sep 2020 22:59:38

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T18:59:12', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'a3c057b4-90af-4c5e-b204-8c6f7a5583ab' User entered 'No (N)'	System	15 Sep 2020 22:59:38
	System	15 Sep 2020 22:59:38

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T18:59:17', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'a3c057b4-90af-4c5e-b204-8c6f7a5583ab' User entered 'None (1)'	System	15 Sep 2020 22:59:38
	System	15 Sep 2020 22:59:38

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T18:59:34', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'a3c057b4-90af-4c5e-b204-8c6f7a5583ab' User entered '15 Sep 2020 18:59'	System	15 Sep 2020 22:59:38
	System	15 Sep 2020 22:59:38

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 3'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:02:55', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'cc6fb78f-d9c0-4676-ae99-b754452cf74a'	System	17 Sep 2020 22:56:24
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 22:56:24

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:02:59', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'cc6fb78f-d9c0-4676-ae99-b754452cf74a' User entered 'No (N)'	System	17 Sep 2020 22:56:24
	System	17 Sep 2020 22:56:24

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:03:02', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'cc6fb78f-d9c0-4676-ae99-b754452cf74a' User entered 'No (N)'	System	17 Sep 2020 22:56:24
	System	17 Sep 2020 22:56:24

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:03:05', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'cc6fb78f-d9c0-4676-ae99-b754452cf74a'	System	17 Sep 2020 22:56:24
User entered 'None (1)'	System	17 Sep 2020 22:56:24

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:03:11', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'cc6fb78f-d9c0-4676-ae99-b754452cf74a' User entered '16 Sep 2020 19:03'	System	17 Sep 2020 22:56:24
	System	17 Sep 2020 22:56:24

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 4'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:57:29', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'bad14116-ae27-4c31-9ef7-8ffc545b6ac7' User entered 'None (1)'	System	17 Sep 2020 22:58:17
	System	17 Sep 2020 22:58:17

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:57:33', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'bad14116-ae27-4c31-9ef7-8ffc545b6ac7' User entered 'No (N)'	System	17 Sep 2020 22:58:17
	System	17 Sep 2020 22:58:17

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:57:39', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'bad14116-ae27-4c31-9ef7-8ffc545b6ac7' User entered 'No (N)'	System	17 Sep 2020 22:58:17
	System	17 Sep 2020 22:58:17

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:58:08', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'bad14116-ae27-4c31-9ef7-8ffc545b6ac7' User entered 'None (1)'	System	17 Sep 2020 22:58:17
	System	17 Sep 2020 22:58:17

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:58:15', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'bad14116-ae27-4c31-9ef7-8ffc545b6ac7' User entered '17 Sep 2020 18:58'	System	17 Sep 2020 22:58:17
	System	17 Sep 2020 22:58:17

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 5'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:33:28', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0a626961-81a3-4e6d-8940-02c7eb0de607'	System	18 Sep 2020 22:33:59
User entered 'None (1)'	System	18 Sep 2020 22:33:59

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:33:31', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0a626961-81a3-4e6d-8940-02c7eb0de607' User entered 'No (N)'	System	18 Sep 2020 22:33:59
	System	18 Sep 2020 22:33:59

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:33:35', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0a626961-81a3-4e6d-8940-02c7eb0de607' User entered 'No (N)'	System	18 Sep 2020 22:33:59
	System	18 Sep 2020 22:33:59

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:33:39', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0a626961-81a3-4e6d-8940-02c7eb0de607' User entered 'None (1)'	System	18 Sep 2020 22:33:59
	System	18 Sep 2020 22:33:59

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:33:50', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0a626961-81a3-4e6d-8940-02c7eb0de607' User entered '18 Sep 2020 18:33'	System	18 Sep 2020 22:33:59
	System	18 Sep 2020 22:33:59

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 6'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:20', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f02222b7-fe9c-446f-9cad-f07c55aa5ce5'	System	19 Sep 2020 23:04:41
User entered 'None (1)'	System	19 Sep 2020 23:04:41

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:25', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f02222b7-fe9c-446f-9cad-f07c55aa5ce5' User entered 'No (N)'	System	19 Sep 2020 23:04:41
	System	19 Sep 2020 23:04:41

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:31', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f02222b7-fe9c-446f-9cad-f07c55aa5ce5' User entered 'No (N)'	System	19 Sep 2020 23:04:41
	System	19 Sep 2020 23:04:41

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:35', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f02222b7-fe9c-446f-9cad-f07c55aa5ce5'	System	19 Sep 2020 23:04:41
User entered 'None (1)'	System	19 Sep 2020 23:04:41

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:38', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f02222b7-fe9c-446f-9cad-f07c55aa5ce5' User entered '19 Sep 2020 19:04'	System	19 Sep 2020 23:04:41
	System	19 Sep 2020 23:04:41

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 7'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:17', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'd160b9a5-a7d4-4e60-819c-1ff0165fb62f' User entered 'None (1)'	System	20 Sep 2020 22:51:38
	System	20 Sep 2020 22:51:38

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:21', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'd160b9a5-a7d4-4e60-819c-1ff0165fb62f' User entered 'No (N)'	System	20 Sep 2020 22:51:38
	System	20 Sep 2020 22:51:38

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:24', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'd160b9a5-a7d4-4e60-819c-1ff0165fb62f' User entered 'No (N)'	System	20 Sep 2020 22:51:38
	System	20 Sep 2020 22:51:38

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:28', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'd160b9a5-a7d4-4e60-819c-1ff0165fb62f' User entered 'None (1)'	System	20 Sep 2020 22:51:38
	System	20 Sep 2020 22:51:38

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:35', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'd160b9a5-a7d4-4e60-819c-1ff0165fb62f' User entered '20 Sep 2020 18:51'	System	20 Sep 2020 22:51:38
	System	20 Sep 2020 22:51:38

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:05:15', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'ac47a29a-c1fd-4c07-a07d-c3b5f5aa21a9' User entered 'None (0)'	System	14 Sep 2020 13:05:43
	System	14 Sep 2020 13:05:43

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:05:17', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'ac47a29a-c1fd-4c07-a07d-c3b5f5aa21a9' User entered 'None (0)'	System	14 Sep 2020 13:05:43
	System	14 Sep 2020 13:05:43

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:05:20', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'ac47a29a-c1fd-4c07-a07d-c3b5f5aa21a9' User entered 'None (0)'	System	14 Sep 2020 13:05:43
	System	14 Sep 2020 13:05:43

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:05:22', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'ac47a29a-c1fd-4c07-a07d-c3b5f5aa21a9' User entered 'None (0)'	System	14 Sep 2020 13:05:43
	System	14 Sep 2020 13:05:43

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:05:24', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'ac47a29a-c1fd-4c07-a07d-c3b5f5aa21a9' User entered 'None (0)'	System	14 Sep 2020 13:05:43
	System	14 Sep 2020 13:05:43

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:05:27', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'ac47a29a-c1fd-4c07-a07d-c3b5f5aa21a9' User entered 'None (0)'	System	14 Sep 2020 13:05:43
	System	14 Sep 2020 13:05:43

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:05:31', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'ac47a29a-c1fd-4c07-a07d-c3b5f5aa21a9' User entered 'No (N)'	System	14 Sep 2020 13:05:43
	System	14 Sep 2020 13:05:43

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T09:05:36', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'ac47a29a-c1fd-4c07-a07d-c3b5f5aa21a9' User entered '14 Sep 2020 09:05'	System	14 Sep 2020 13:05:43
	System	14 Sep 2020 13:05:43

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Sep 2020 08:48'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Sep 2020 11:18'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:02:08', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '771a7a95-5d5b-4d7b-9cd2-bb8e175d3fb4' User entered 'None (0)'	System	14 Sep 2020 23:02:40
	System	14 Sep 2020 23:02:40

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:02:12', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '771a7a95-5d5b-4d7b-9cd2-bb8e175d3fb4' User entered 'None (0)'	System	14 Sep 2020 23:02:40
	System	14 Sep 2020 23:02:40

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:02:15', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '771a7a95-5d5b-4d7b-9cd2-bb8e175d3fb4' User entered 'None (0)'	System	14 Sep 2020 23:02:40
	System	14 Sep 2020 23:02:40

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:02:18', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '771a7a95-5d5b-4d7b-9cd2-bb8e175d3fb4' User entered 'None (0)'	System	14 Sep 2020 23:02:40
	System	14 Sep 2020 23:02:40

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:02:21', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '771a7a95-5d5b-4d7b-9cd2-bb8e175d3fb4' User entered 'None (0)'	System	14 Sep 2020 23:02:40
	System	14 Sep 2020 23:02:40

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:02:23', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '771a7a95-5d5b-4d7b-9cd2-bb8e175d3fb4' User entered 'None (0)'	System	14 Sep 2020 23:02:40
	System	14 Sep 2020 23:02:40

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:02:31', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '771a7a95-5d5b-4d7b-9cd2-bb8e175d3fb4' User entered 'No (N)'	System	14 Sep 2020 23:02:40
	System	14 Sep 2020 23:02:40

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-14T19:02:38', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '771a7a95-5d5b-4d7b-9cd2-bb8e175d3fb4' User entered '14 Sep 2020 19:02'	System	14 Sep 2020 23:02:40
	System	14 Sep 2020 23:02:40

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Sep 2020 12:13'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 2'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T18:59:48', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0493644a-0119-46e0-85a0-28960aaff438' User entered 'None (0)'	System	15 Sep 2020 23:00:19
	System	15 Sep 2020 23:00:19

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T18:59:52', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0493644a-0119-46e0-85a0-28960aaff438' User entered 'None (0)'	System	15 Sep 2020 23:00:19
	System	15 Sep 2020 23:00:19

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T18:59:55', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0493644a-0119-46e0-85a0-28960aaff438' User entered 'None (0)'	System	15 Sep 2020 23:00:19
	System	15 Sep 2020 23:00:19

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T18:59:58', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0493644a-0119-46e0-85a0-28960aaff438' User entered 'None (0)'	System	15 Sep 2020 23:00:19
	System	15 Sep 2020 23:00:19

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T19:00:01', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0493644a-0119-46e0-85a0-28960aaff438' User entered 'None (0)'	System	15 Sep 2020 23:00:19
	System	15 Sep 2020 23:00:19

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T19:00:07', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0493644a-0119-46e0-85a0-28960aaff438' User entered 'None (0)'	System	15 Sep 2020 23:00:19
	System	15 Sep 2020 23:00:19

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T19:00:10', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0493644a-0119-46e0-85a0-28960aaff438' User entered 'No (N)'	System	15 Sep 2020 23:00:19
	System	15 Sep 2020 23:00:19

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-15T19:00:17', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0493644a-0119-46e0-85a0-28960aaff438' User entered '15 Sep 2020 19:00'	System	15 Sep 2020 23:00:19
	System	15 Sep 2020 23:00:19

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 3'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:03:17', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'b405199c-1900-4ef0-8d5d-53cce5aa7cc0' User entered 'None (0)'	System	17 Sep 2020 22:56:26
	System	17 Sep 2020 22:56:26

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:03:19', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'b405199c-1900-4ef0-8d5d-53cce5aa7cc0' User entered 'None (0)'	System	17 Sep 2020 22:56:26
	System	17 Sep 2020 22:56:26

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:03:22', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'b405199c-1900-4ef0-8d5d-53cce5aa7cc0' User entered 'None (0)'	System	17 Sep 2020 22:56:26
	System	17 Sep 2020 22:56:26

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:03:24', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'b405199c-1900-4ef0-8d5d-53cce5aa7cc0' User entered 'None (0)'	System	17 Sep 2020 22:56:26
	System	17 Sep 2020 22:56:26

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:03:26', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'b405199c-1900-4ef0-8d5d-53cce5aa7cc0' User entered 'None (0)'	System	17 Sep 2020 22:56:26
	System	17 Sep 2020 22:56:26

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:03:29', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'b405199c-1900-4ef0-8d5d-53cce5aa7cc0' User entered 'None (0)'	System	17 Sep 2020 22:56:26
	System	17 Sep 2020 22:56:26

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:03:32', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'b405199c-1900-4ef0-8d5d-53cce5aa7cc0' User entered 'No (N)'	System	17 Sep 2020 22:56:26
	System	17 Sep 2020 22:56:26

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-16T19:03:39', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'b405199c-1900-4ef0-8d5d-53cce5aa7cc0' User entered '16 Sep 2020 19:03'	System	17 Sep 2020 22:56:26
	System	17 Sep 2020 22:56:26

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 4'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:58:21', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'abb43ccd-9e1c-4868-8e8f-906ad0c0a02b' User entered 'None (0)'	System	17 Sep 2020 22:59:22
	System	17 Sep 2020 22:59:22

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:58:41', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'abb43ccd-9e1c-4868-8e8f-906ad0c0a02b' User entered 'None (0)'	System	17 Sep 2020 22:59:22
	System	17 Sep 2020 22:59:22

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:58:44', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'abb43ccd-9e1c-4868-8e8f-906ad0c0a02b' User entered 'None (0)'	System	17 Sep 2020 22:59:22
	System	17 Sep 2020 22:59:22

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:58:47', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'abb43ccd-9e1c-4868-8e8f-906ad0c0a02b' User entered 'None (0)'	System	17 Sep 2020 22:59:22
	System	17 Sep 2020 22:59:22

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:58:49', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'abb43ccd-9e1c-4868-8e8f-906ad0c0a02b' User entered 'None (0)'	System	17 Sep 2020 22:59:22
	System	17 Sep 2020 22:59:22

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:58:52', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'abb43ccd-9e1c-4868-8e8f-906ad0c0a02b' User entered 'None (0)'	System	17 Sep 2020 22:59:22
	System	17 Sep 2020 22:59:22

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:58:55', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'abb43ccd-9e1c-4868-8e8f-906ad0c0a02b' User entered 'No (N)'	System	17 Sep 2020 22:59:22
	System	17 Sep 2020 22:59:22

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-17T18:59:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'abb43ccd-9e1c-4868-8e8f-906ad0c0a02b' User entered '17 Sep 2020 18:59'	System	17 Sep 2020 22:59:22
	System	17 Sep 2020 22:59:22

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 5'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:33:55', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9ae4c899-f7e9-4221-8e77-26d9def7ba51' User entered 'None (0)'	System	18 Sep 2020 22:34:21
	System	18 Sep 2020 22:34:21

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:33:58', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9ae4c899-f7e9-4221-8e77-26d9def7ba51' User entered 'None (0)'	System	18 Sep 2020 22:34:21
	System	18 Sep 2020 22:34:21

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:34:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9ae4c899-f7e9-4221-8e77-26d9def7ba51' User entered 'None (0)'	System	18 Sep 2020 22:34:21
	System	18 Sep 2020 22:34:21

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:34:03', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9ae4c899-f7e9-4221-8e77-26d9def7ba51' User entered 'None (0)'	System	18 Sep 2020 22:34:21
	System	18 Sep 2020 22:34:21

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:34:06', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9ae4c899-f7e9-4221-8e77-26d9def7ba51' User entered 'None (0)'	System	18 Sep 2020 22:34:21
	System	18 Sep 2020 22:34:21

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:34:08', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9ae4c899-f7e9-4221-8e77-26d9def7ba51' User entered 'None (0)'	System	18 Sep 2020 22:34:21
	System	18 Sep 2020 22:34:21

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:34:12', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9ae4c899-f7e9-4221-8e77-26d9def7ba51' User entered 'No (N)'	System	18 Sep 2020 22:34:21
	System	18 Sep 2020 22:34:21

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-18T18:34:19', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9ae4c899-f7e9-4221-8e77-26d9def7ba51' User entered '18 Sep 2020 18:34'	System	18 Sep 2020 22:34:21
	System	18 Sep 2020 22:34:21

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 6'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:43', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '69dfdb4d-721a-4f68-9470-dee472cdf2c7' User entered 'None (0)'	System	19 Sep 2020 23:05:07
	System	19 Sep 2020 23:05:07

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:45', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '69dfdb4d-721a-4f68-9470-dee472cdf2c7' User entered 'None (0)'	System	19 Sep 2020 23:05:07
	System	19 Sep 2020 23:05:07

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:48', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '69dfdb4d-721a-4f68-9470-dee472cdf2c7' User entered 'None (0)'	System	19 Sep 2020 23:05:07
	System	19 Sep 2020 23:05:07

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:50', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '69dfdb4d-721a-4f68-9470-dee472cdf2c7' User entered 'None (0)'	System	19 Sep 2020 23:05:07
	System	19 Sep 2020 23:05:07

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:53', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '69dfdb4d-721a-4f68-9470-dee472cdf2c7' User entered 'None (0)'	System	19 Sep 2020 23:05:07
	System	19 Sep 2020 23:05:07

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:55', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '69dfdb4d-721a-4f68-9470-dee472cdf2c7' User entered 'None (0)'	System	19 Sep 2020 23:05:07
	System	19 Sep 2020 23:05:07

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:04:58', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '69dfdb4d-721a-4f68-9470-dee472cdf2c7' User entered 'No (N)'	System	19 Sep 2020 23:05:07
	System	19 Sep 2020 23:05:07

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-19T19:05:01', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '69dfdb4d-721a-4f68-9470-dee472cdf2c7' User entered '19 Sep 2020 19:05'	System	19 Sep 2020 23:05:07
	System	19 Sep 2020 23:05:07

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 7'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:40', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1e8d0477-9712-4a0e-aa47-ad5393599894' User entered 'None (0)'	System	20 Sep 2020 22:52:08
	System	20 Sep 2020 22:52:08

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:43', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1e8d0477-9712-4a0e-aa47-ad5393599894' User entered 'None (0)'	System	20 Sep 2020 22:52:08
	System	20 Sep 2020 22:52:08

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:46', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1e8d0477-9712-4a0e-aa47-ad5393599894' User entered 'None (0)'	System	20 Sep 2020 22:52:08
	System	20 Sep 2020 22:52:08

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:49', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1e8d0477-9712-4a0e-aa47-ad5393599894' User entered 'None (0)'	System	20 Sep 2020 22:52:08
	System	20 Sep 2020 22:52:08

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:52', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1e8d0477-9712-4a0e-aa47-ad5393599894' User entered 'None (0)'	System	20 Sep 2020 22:52:08
	System	20 Sep 2020 22:52:08

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:55', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1e8d0477-9712-4a0e-aa47-ad5393599894' User entered 'None (0)'	System	20 Sep 2020 22:52:08
	System	20 Sep 2020 22:52:08

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:51:58', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1e8d0477-9712-4a0e-aa47-ad5393599894' User entered 'No (N)'	System	20 Sep 2020 22:52:08
	System	20 Sep 2020 22:52:08

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-09-20T18:52:05', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1e8d0477-9712-4a0e-aa47-ad5393599894' User entered '20 Sep 2020 18:52'	System	20 Sep 2020 22:52:08
	System	20 Sep 2020 22:52:08

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 12:57:23

US3432497

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 18:33:24

US3432497

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:42
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 18:33:24

US3432497

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Sep 2020 18:33:24

US3432497

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:02:42
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:33:24

US3432497

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:03:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 18:33:29

US3432497

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'I'	System	21 Sep 2020 18:33:29

US3432497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:05:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 14:09:11

US3432497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:05:42
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 14:09:11

US3432497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:05:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Sep 2020 14:09:11

US3432497

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:05:42
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 14:09:11

US3432497

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:39:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 13:58:37

US3432497

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'I'	System	05 Oct 2020 13:58:37

US3432497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:27:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 13:58:45

US3432497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:27:22
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 13:58:45

US3432497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:27:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 13:58:45

US3432497

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:27:22
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 13:58:45

US3432497

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:27:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 13:58:51

US3432497

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'I'	System	05 Oct 2020 13:58:51

US3432497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:39:17
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is present in GCL but data not present in EDC, please clarify or reconcile ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:29:58
Query 'Per GCL Lab reconciliation: SWAB sample with collection date of 14Oct2020 recorded for Visit 2 Day 29 in PPD central lab. However, data is missing in EDC. Please reconcile. Else clarify.' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:29:57
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is present in GCL but data not present in EDC, please clarify or reconcile ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:16:16
User opened query 'Per GCL Lab reconciliation: SWAB sample with collection date of 14Oct2020 recorded for Visit 2 Day 29 in PPD central lab. However, data is missing in EDC. Please reconcile. Else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:18:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:32:40

US3432497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:39:17
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 21:32:40

US3432497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:39:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Oct 2020 21:32:40

US3432497

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'VISIT2'	System	14 Oct 2020 21:32:40

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '16:10'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered '14 Oct 2020 16:10'	System	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '37.1' C	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '69'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'bpm'	System	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '16'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'breaths/min'	System	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '121'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'mmHg'	System	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '79'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'mmHg'	System	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '17:21'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered '14 Oct 2020 17:21'	System	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '36.7' C	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 17:57:27
User closed query 'Per source: Oral: please check and edit' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 17:57:25
Query 'Per source: Oral: please check and edit' answered by data change (Site from CRA).	System	09 Dec 2020 14:49:53
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 14:49:53
User opened query 'Per source: Oral: please check and edit' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:40:33
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered 'Axillary (Axillary)'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '63'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'bpm'	System	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '16'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'breaths/min'	System	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '130'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'mmHg'	System	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:40:03
User entered '78'	(b) (4), (b) (6)	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'mmHg'	System	14 Oct 2020 21:32:26

US3432497

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:32:51

US3432497

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:08
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 21:32:51

US3432497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:25:53

US3432497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:21
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 21:25:53

US3432497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

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)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:21
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 21:25:53

US3432497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'MRNA-1273 OR PLACEBO'	System	14 Oct 2020 21:25:53

US3432497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:21
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 21:25:53

US3432497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:21
User entered '16:50'	(b) (4), (b) (6)	14 Oct 2020 21:25:53

US3432497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered '14 Oct 2020 16:50'	System	14 Oct 2020 21:25:53

US3432497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:21
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	14 Oct 2020 21:25:53

US3432497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:21
User entered 'ONCE'	System	14 Oct 2020 21:25:53

US3432497

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'INTRAMUSCULAR'	System	14 Oct 2020 21:25:53

US3432497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 14:57:35

US3432497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:40
User entered '14 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 14:57:35

US3432497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:40
User entered '16:35'	(b) (4), (b) (6)	04 Nov 2020 14:57:35

US3432497

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered '14 Oct 2020 16:35'	System	04 Nov 2020 14:57:35

US3432497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:39:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:46
User entered '14 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 14:57:56

US3432497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Nov 2020 14:57:56

US3432497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 14:57:56

US3432497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:46
User entered '16:40'	(b) (4), (b) (6)	04 Nov 2020 14:57:56

US3432497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered '14 Oct 2020 16:40'	System	04 Nov 2020 14:57:56

US3432497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Nov 2020 14:57:56

US3432497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:46
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 14:57:56

US3432497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:46
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 14:57:56

US3432497

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered empty.	System	04 Nov 2020 14:57:56

US3432497

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:41:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:33:02

US3432497

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'I'	System	14 Oct 2020 21:33:02

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:26:48', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'da776bdb-f252-43dd-9578-1bcf4f3db938' User entered 'Yes (Y)'	System	14 Oct 2020 21:27:09
	System	14 Oct 2020 21:27:09

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:26:54', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'da776bdb-f252-43dd-9578-1bcf4f3db938' User entered '98.2'	System	14 Oct 2020 21:27:09
	System	14 Oct 2020 21:27:09

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'da776bdb-f252-43dd-9578-1bcf4f3db938'	System	14 Oct 2020 21:27:09
User entered 'No (N)'	System	14 Oct 2020 21:27:09

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:06', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'da776bdb-f252-43dd-9578-1bcf4f3db938' User entered '14 Oct 2020 17:27'	System	14 Oct 2020 21:27:09
	System	14 Oct 2020 21:27:09

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Oct 2020 17:10'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Oct 2020 19:40'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:39:51', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e2e58c6f-025b-42d2-9b80-15dcc20ed942' User entered 'Yes (Y)'	System	15 Oct 2020 00:40:13
	System	15 Oct 2020 00:40:13

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:40:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e2e58c6f-025b-42d2-9b80-15dcc20ed942' User entered '96.9'	System	15 Oct 2020 00:40:13
	System	15 Oct 2020 00:40:13

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:40:06', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e2e58c6f-025b-42d2-9b80-15dcc20ed942'	System	15 Oct 2020 00:40:13
User entered 'No (N)'	System	15 Oct 2020 00:40:13

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:40:11', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e2e58c6f-025b-42d2-9b80-15dcc20ed942' User entered '14 Oct 2020 20:40'	System	15 Oct 2020 00:40:13
	System	15 Oct 2020 00:40:13

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Oct 2020 20:35'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 2'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:03:14', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '6ad468f0-13c6-4219-9149-36cb877edd71' User entered 'Yes (Y)'	System	15 Oct 2020 22:03:57
	System	15 Oct 2020 22:03:57

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:03:25', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '6ad468f0-13c6-4219-9149-36cb877edd71' User entered '100.2'	System	15 Oct 2020 22:03:57
	System	15 Oct 2020 22:03:57

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:03:32', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '6ad468f0-13c6-4219-9149-36cb877edd71' User entered 'Yes (Y)'	System	15 Oct 2020 22:03:57
	System	15 Oct 2020 22:03:57

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
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 'confirmed with pt, took ibuprofen to treat fever' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 09:31:45
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).	Kathleen Garvey (b) (4)	04 Nov 2020 13:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:03:44', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '6ad468f0-13c6-4219-9149-36cb877edd71'	(b) (4)	
User entered '1'	System	15 Oct 2020 22:03:57
	System	15 Oct 2020 22:03:57
	System	15 Oct 2020 22:03:57

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:03:44', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '6ad468f0-13c6-4219-9149-36cb877edd71' User entered '0'	System	15 Oct 2020 22:03:57
	System	15 Oct 2020 22:03:57

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:03:51', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '6ad468f0-13c6-4219-9149-36cb877edd71' User entered '15 Oct 2020 18:03'	System	15 Oct 2020 22:03:57
	System	15 Oct 2020 22:03:57

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 3'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:07', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '03478be8-ca90-496c-94f1-1eb56517cddc' User entered 'Yes (Y)'	System	16 Oct 2020 22:42:34
	System	16 Oct 2020 22:42:34

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:15', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '03478be8-ca90-496c-94f1-1eb56517cddc' User entered '99.1'	System	16 Oct 2020 22:42:34
	System	16 Oct 2020 22:42:34

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:19', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '03478be8-ca90-496c-94f1-1eb56517cddc' User entered 'No (N)'	System	16 Oct 2020 22:42:34
	System	16 Oct 2020 22:42:34

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:23', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '03478be8-ca90-496c-94f1-1eb56517cddc' User entered '16 Oct 2020 18:42'	System	16 Oct 2020 22:42:34
	System	16 Oct 2020 22:42:34

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 4'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:42:55', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '08ccb316-88ea-4faa-8df5-9b38f86e0238' User entered 'Yes (Y)'	System	17 Oct 2020 23:43:16
	System	17 Oct 2020 23:43:16

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:05', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '08ccb316-88ea-4faa-8df5-9b38f86e0238' User entered '97.5'	System	17 Oct 2020 23:43:16
	System	17 Oct 2020 23:43:16

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:10', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '08ccb316-88ea-4faa-8df5-9b38f86e0238' User entered 'No (N)'	System	17 Oct 2020 23:43:16
	System	17 Oct 2020 23:43:16

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:13', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '08ccb316-88ea-4faa-8df5-9b38f86e0238' User entered '17 Oct 2020 19:43'	System	17 Oct 2020 23:43:16
	System	17 Oct 2020 23:43:16

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 5'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:03:28', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f3531091-0b25-4907-81b6-60f5ebc7e28a' User entered 'Yes (Y)'	System	18 Oct 2020 23:03:44
	System	18 Oct 2020 23:03:44

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:03:35', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f3531091-0b25-4907-81b6-60f5ebc7e28a' User entered '98.5'	System	18 Oct 2020 23:03:44
	System	18 Oct 2020 23:03:44

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:03:38', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f3531091-0b25-4907-81b6-60f5ebc7e28a' User entered 'No (N)'	System	18 Oct 2020 23:03:44
	System	18 Oct 2020 23:03:44

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:03:42', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f3531091-0b25-4907-81b6-60f5ebc7e28a' User entered '18 Oct 2020 19:03'	System	18 Oct 2020 23:03:44
	System	18 Oct 2020 23:03:44

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 6'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:26:43', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '4030d652-2876-4265-ae93-93ec5c376de3' User entered 'Yes (Y)'	System	20 Oct 2020 00:27:03
	System	20 Oct 2020 00:27:03

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:26:49', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '4030d652-2876-4265-ae93-93ec5c376de3' User entered '96.7'	System	20 Oct 2020 00:27:03
	System	20 Oct 2020 00:27:03

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:26:53', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '4030d652-2876-4265-ae93-93ec5c376de3' User entered 'No (N)'	System	20 Oct 2020 00:27:03
	System	20 Oct 2020 00:27:03

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:26:58', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '4030d652-2876-4265-ae93-93ec5c376de3' User entered '19 Oct 2020 20:26'	System	20 Oct 2020 00:27:03
	System	20 Oct 2020 00:27:03

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 7'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:56:39', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1d5aac37-4660-475b-b0e2-08ca26b4709d' User entered 'Yes (Y)'	System	20 Oct 2020 22:56:55
	System	20 Oct 2020 22:56:55

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:56:45', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1d5aac37-4660-475b-b0e2-08ca26b4709d' User entered '97.7'	System	20 Oct 2020 22:56:55
	System	20 Oct 2020 22:56:55

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:56:48', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1d5aac37-4660-475b-b0e2-08ca26b4709d' User entered 'No (N)'	System	20 Oct 2020 22:56:55
	System	20 Oct 2020 22:56:55

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:56:51', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1d5aac37-4660-475b-b0e2-08ca26b4709d' User entered '20 Oct 2020 18:56'	System	20 Oct 2020 22:56:55
	System	20 Oct 2020 22:56:55

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:13', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '2cd07527-d787-442b-888c-34146eec4471' User entered 'None (1)'	System	14 Oct 2020 21:27:34
	System	14 Oct 2020 21:27:34

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:21', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '2cd07527-d787-442b-888c-34146eec4471' User entered 'No (N)'	System	14 Oct 2020 21:27:34
	System	14 Oct 2020 21:27:34

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:24', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '2cd07527-d787-442b-888c-34146eec4471' User entered 'No (N)'	System	14 Oct 2020 21:27:34
	System	14 Oct 2020 21:27:34

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:27', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '2cd07527-d787-442b-888c-34146eec4471' User entered 'None (1)'	System	14 Oct 2020 21:27:34
	System	14 Oct 2020 21:27:34

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:30', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '2cd07527-d787-442b-888c-34146eec4471' User entered '14 Oct 2020 17:27'	System	14 Oct 2020 21:27:34
	System	14 Oct 2020 21:27:34

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Oct 2020 17:10'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Oct 2020 19:40'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:40:19', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '438855e0-ecc6-4771-babe-055b19c16c51' User entered 'None (1)'	System	15 Oct 2020 00:40:56
	System	15 Oct 2020 00:40:56

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:40:43', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '438855e0-ecc6-4771-babe-055b19c16c51' User entered 'No (N)'	System	15 Oct 2020 00:40:56
	System	15 Oct 2020 00:40:56

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:40:47', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '438855e0-ecc6-4771-babe-055b19c16c51' User entered 'No (N)'	System	15 Oct 2020 00:40:56
	System	15 Oct 2020 00:40:56

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:40:50', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '438855e0-ecc6-4771-babe-055b19c16c51' User entered 'None (1)'	System	15 Oct 2020 00:40:56
	System	15 Oct 2020 00:40:56

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:40:54', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '438855e0-ecc6-4771-babe-055b19c16c51' User entered '14 Oct 2020 20:40'	System	15 Oct 2020 00:40:56
	System	15 Oct 2020 00:40:56

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Oct 2020 20:35'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 2'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '925a3dbe-280a-4426-9b98-e8250bc69f29'	System	15 Oct 2020 22:04:23
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 22:04:23

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:04:04', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '925a3dbe-280a-4426-9b98-e8250bc69f29' User entered 'No (N)'	System	15 Oct 2020 22:04:23
	System	15 Oct 2020 22:04:23

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:04:08', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '925a3dbe-280a-4426-9b98-e8250bc69f29' User entered 'No (N)'	System	15 Oct 2020 22:04:23
	System	15 Oct 2020 22:04:23

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:04:11', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '925a3dbe-280a-4426-9b98-e8250bc69f29'	System	15 Oct 2020 22:04:23
User entered 'None (1)'	System	15 Oct 2020 22:04:23

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:04:21', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '925a3dbe-280a-4426-9b98-e8250bc69f29' User entered '15 Oct 2020 18:04'	System	15 Oct 2020 22:04:23
	System	15 Oct 2020 22:04:23

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 3'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:29', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0514d2c5-3032-48a2-8768-6921c1488c8a'	System	16 Oct 2020 22:42:50
User entered 'None (1)'	System	16 Oct 2020 22:42:50

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:33', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0514d2c5-3032-48a2-8768-6921c1488c8a' User entered 'No (N)'	System	16 Oct 2020 22:42:50
	System	16 Oct 2020 22:42:50

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:36', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0514d2c5-3032-48a2-8768-6921c1488c8a' User entered 'No (N)'	System	16 Oct 2020 22:42:50
	System	16 Oct 2020 22:42:50

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:40', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0514d2c5-3032-48a2-8768-6921c1488c8a'	System	16 Oct 2020 22:42:50
User entered 'None (1)'	System	16 Oct 2020 22:42:50

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:43', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '0514d2c5-3032-48a2-8768-6921c1488c8a' User entered '16 Oct 2020 18:42'	System	16 Oct 2020 22:42:50
	System	16 Oct 2020 22:42:50

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 4'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:21', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '52a6746d-20aa-4a94-97e7-000db69caee7' User entered 'None (1)'	System	17 Oct 2020 23:43:46
	System	17 Oct 2020 23:43:46

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:24', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '52a6746d-20aa-4a94-97e7-000db69caee7' User entered 'No (N)'	System	17 Oct 2020 23:43:46
	System	17 Oct 2020 23:43:46

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:26', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '52a6746d-20aa-4a94-97e7-000db69caee7' User entered 'No (N)'	System	17 Oct 2020 23:43:46
	System	17 Oct 2020 23:43:46

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:29', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '52a6746d-20aa-4a94-97e7-000db69caee7' User entered 'None (1)'	System	17 Oct 2020 23:43:46
	System	17 Oct 2020 23:43:46

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:32', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '52a6746d-20aa-4a94-97e7-000db69caee7' User entered '17 Oct 2020 19:43'	System	17 Oct 2020 23:43:46
	System	17 Oct 2020 23:43:46

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 5'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:03:47', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c1d1fbef-10da-4be8-a863-e9c4bb970d96'	System	18 Oct 2020 23:04:04
User entered 'None (1)'	System	18 Oct 2020 23:04:04

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:03:50', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c1d1fbef-10da-4be8-a863-e9c4bb970d96'	System	18 Oct 2020 23:04:04
User entered 'No (N)'	System	18 Oct 2020 23:04:04

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:03:53', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c1d1fbef-10da-4be8-a863-e9c4bb970d96'	System	18 Oct 2020 23:04:04
User entered 'No (N)'	System	18 Oct 2020 23:04:04

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:03:56', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c1d1fbef-10da-4be8-a863-e9c4bb970d96'	System	18 Oct 2020 23:04:04
User entered 'None (1)'	System	18 Oct 2020 23:04:04

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:03:59', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c1d1fbef-10da-4be8-a863-e9c4bb970d96' User entered '18 Oct 2020 19:03'	System	18 Oct 2020 23:04:04
	System	18 Oct 2020 23:04:04

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 6'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:27:04', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c93d101b-e3f7-42c9-891b-ddfa4a0cf8e0' User entered 'None (1)'	System	20 Oct 2020 00:27:21
	System	20 Oct 2020 00:27:21

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:27:07', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c93d101b-e3f7-42c9-891b-ddfa4a0cf8e0' User entered 'No (N)'	System	20 Oct 2020 00:27:21
	System	20 Oct 2020 00:27:21

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:27:11', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c93d101b-e3f7-42c9-891b-ddfa4a0cf8e0' User entered 'No (N)'	System	20 Oct 2020 00:27:21
	System	20 Oct 2020 00:27:21

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:27:14', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c93d101b-e3f7-42c9-891b-ddfa4a0cf8e0' User entered 'None (1)'	System	20 Oct 2020 00:27:21
	System	20 Oct 2020 00:27:21

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:27:17', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c93d101b-e3f7-42c9-891b-ddfa4a0cf8e0' User entered '19 Oct 2020 20:27'	System	20 Oct 2020 00:27:21
	System	20 Oct 2020 00:27:21

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 7'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:56:58', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '462fd071-7f48-44e6-975f-98f896419374' User entered 'None (1)'	System	20 Oct 2020 22:57:12
	System	20 Oct 2020 22:57:12

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:57:01', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '462fd071-7f48-44e6-975f-98f896419374' User entered 'No (N)'	System	20 Oct 2020 22:57:12
	System	20 Oct 2020 22:57:12

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:57:03', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '462fd071-7f48-44e6-975f-98f896419374' User entered 'No (N)'	System	20 Oct 2020 22:57:12
	System	20 Oct 2020 22:57:12

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:57:06', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '462fd071-7f48-44e6-975f-98f896419374' User entered 'None (1)'	System	20 Oct 2020 22:57:12
	System	20 Oct 2020 22:57:12

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:57:09', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '462fd071-7f48-44e6-975f-98f896419374' User entered '20 Oct 2020 18:57'	System	20 Oct 2020 22:57:12
	System	20 Oct 2020 22:57:12

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:35', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '294b1ae2-cd0e-4d39-989a-bf64221fd7c1' User entered 'None (0)'	System	14 Oct 2020 21:27:54
	System	14 Oct 2020 21:27:54

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:37', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '294b1ae2-cd0e-4d39-989a-bf64221fd7c1' User entered 'None (0)'	System	14 Oct 2020 21:27:54
	System	14 Oct 2020 21:27:54

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:40', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '294b1ae2-cd0e-4d39-989a-bf64221fd7c1' User entered 'None (0)'	System	14 Oct 2020 21:27:54
	System	14 Oct 2020 21:27:54

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:42', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '294b1ae2-cd0e-4d39-989a-bf64221fd7c1' User entered 'None (0)'	System	14 Oct 2020 21:27:54
	System	14 Oct 2020 21:27:54

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:44', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '294b1ae2-cd0e-4d39-989a-bf64221fd7c1' User entered 'None (0)'	System	14 Oct 2020 21:27:54
	System	14 Oct 2020 21:27:54

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:46', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '294b1ae2-cd0e-4d39-989a-bf64221fd7c1' User entered 'None (0)'	System	14 Oct 2020 21:27:54
	System	14 Oct 2020 21:27:54

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:49', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '294b1ae2-cd0e-4d39-989a-bf64221fd7c1' User entered 'No (N)'	System	14 Oct 2020 21:27:54
	System	14 Oct 2020 21:27:54

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T17:27:53', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '294b1ae2-cd0e-4d39-989a-bf64221fd7c1' User entered '14 Oct 2020 17:27'	System	14 Oct 2020 21:27:54
	System	14 Oct 2020 21:27:54

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Oct 2020 17:10'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Oct 2020 19:40'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:40:59', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e99df5be-67f0-40a8-be9f-4b7f4ca039e4' User entered 'None (0)'	System	15 Oct 2020 00:41:24
	System	15 Oct 2020 00:41:24

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:41:02', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e99df5be-67f0-40a8-be9f-4b7f4ca039e4' User entered 'None (0)'	System	15 Oct 2020 00:41:24
	System	15 Oct 2020 00:41:24

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:41:04', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e99df5be-67f0-40a8-be9f-4b7f4ca039e4' User entered 'None (0)'	System	15 Oct 2020 00:41:24
	System	15 Oct 2020 00:41:24

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:41:07', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e99df5be-67f0-40a8-be9f-4b7f4ca039e4' User entered 'None (0)'	System	15 Oct 2020 00:41:24
	System	15 Oct 2020 00:41:24

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:41:09', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e99df5be-67f0-40a8-be9f-4b7f4ca039e4' User entered 'None (0)'	System	15 Oct 2020 00:41:24
	System	15 Oct 2020 00:41:24

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:41:12', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e99df5be-67f0-40a8-be9f-4b7f4ca039e4' User entered 'None (0)'	System	15 Oct 2020 00:41:24
	System	15 Oct 2020 00:41:24

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:41:16', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e99df5be-67f0-40a8-be9f-4b7f4ca039e4' User entered 'No (N)'	System	15 Oct 2020 00:41:24
	System	15 Oct 2020 00:41:24

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-14T20:41:19', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e99df5be-67f0-40a8-be9f-4b7f4ca039e4' User entered '14 Oct 2020 20:41'	System	15 Oct 2020 00:41:24
	System	15 Oct 2020 00:41:24

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '14 Oct 2020 20:35'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 2'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:04:29', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '967273c9-618c-40c5-a6ce-a50e9f3652bf' User entered 'No interference with activity (1)'	System	15 Oct 2020 22:06:03
	System	15 Oct 2020 22:06:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:04:47', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '967273c9-618c-40c5-a6ce-a50e9f3652bf' User entered 'None (0)'	System	15 Oct 2020 22:06:03
	System	15 Oct 2020 22:06:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:05:44', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '967273c9-618c-40c5-a6ce-a50e9f3652bf' User entered 'None (0)'	System	15 Oct 2020 22:06:03
	System	15 Oct 2020 22:06:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:05:01', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '967273c9-618c-40c5-a6ce-a50e9f3652bf' User entered 'None (0)'	System	15 Oct 2020 22:06:03
	System	15 Oct 2020 22:06:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:05:04', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '967273c9-618c-40c5-a6ce-a50e9f3652bf' User entered 'None (0)'	System	15 Oct 2020 22:06:03
	System	15 Oct 2020 22:06:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:05:15', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '967273c9-618c-40c5-a6ce-a50e9f3652bf' User entered 'None (0)'	System	15 Oct 2020 22:06:03
	System	15 Oct 2020 22:06:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:05:21', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '967273c9-618c-40c5-a6ce-a50e9f3652bf' User entered 'No (N)'	System	15 Oct 2020 22:06:03
	System	15 Oct 2020 22:06:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-15T18:05:58', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '967273c9-618c-40c5-a6ce-a50e9f3652bf' User entered '15 Oct 2020 18:05'	System	15 Oct 2020 22:06:03
	System	15 Oct 2020 22:06:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 3'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:48', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '08a1bc50-390c-48d6-ae75-b0a96aa0462a' User entered 'None (0)'	System	16 Oct 2020 22:43:16
	System	16 Oct 2020 22:43:16

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:51', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '08a1bc50-390c-48d6-ae75-b0a96aa0462a' User entered 'None (0)'	System	16 Oct 2020 22:43:16
	System	16 Oct 2020 22:43:16

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:53', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '08a1bc50-390c-48d6-ae75-b0a96aa0462a' User entered 'None (0)'	System	16 Oct 2020 22:43:16
	System	16 Oct 2020 22:43:16

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:56', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '08a1bc50-390c-48d6-ae75-b0a96aa0462a' User entered 'None (0)'	System	16 Oct 2020 22:43:16
	System	16 Oct 2020 22:43:16

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:42:59', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '08a1bc50-390c-48d6-ae75-b0a96aa0462a' User entered 'None (0)'	System	16 Oct 2020 22:43:16
	System	16 Oct 2020 22:43:16

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:43:02', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '08a1bc50-390c-48d6-ae75-b0a96aa0462a' User entered 'None (0)'	System	16 Oct 2020 22:43:16
	System	16 Oct 2020 22:43:16

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:43:06', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '08a1bc50-390c-48d6-ae75-b0a96aa0462a' User entered 'No (N)'	System	16 Oct 2020 22:43:16
	System	16 Oct 2020 22:43:16

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-16T18:43:09', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '08a1bc50-390c-48d6-ae75-b0a96aa0462a' User entered '16 Oct 2020 18:43'	System	16 Oct 2020 22:43:16
	System	16 Oct 2020 22:43:16

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 4'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:38', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9c2e4565-d9cf-4bb0-b90b-84e8a00dd430' User entered 'None (0)'	System	17 Oct 2020 23:44:03
	System	17 Oct 2020 23:44:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:41', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9c2e4565-d9cf-4bb0-b90b-84e8a00dd430' User entered 'None (0)'	System	17 Oct 2020 23:44:03
	System	17 Oct 2020 23:44:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:44', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9c2e4565-d9cf-4bb0-b90b-84e8a00dd430' User entered 'None (0)'	System	17 Oct 2020 23:44:03
	System	17 Oct 2020 23:44:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:46', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9c2e4565-d9cf-4bb0-b90b-84e8a00dd430' User entered 'None (0)'	System	17 Oct 2020 23:44:03
	System	17 Oct 2020 23:44:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:48', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9c2e4565-d9cf-4bb0-b90b-84e8a00dd430' User entered 'None (0)'	System	17 Oct 2020 23:44:03
	System	17 Oct 2020 23:44:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:51', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9c2e4565-d9cf-4bb0-b90b-84e8a00dd430' User entered 'None (0)'	System	17 Oct 2020 23:44:03
	System	17 Oct 2020 23:44:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:54', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9c2e4565-d9cf-4bb0-b90b-84e8a00dd430' User entered 'No (N)'	System	17 Oct 2020 23:44:03
	System	17 Oct 2020 23:44:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-17T19:43:57', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '9c2e4565-d9cf-4bb0-b90b-84e8a00dd430' User entered '17 Oct 2020 19:43'	System	17 Oct 2020 23:44:03
	System	17 Oct 2020 23:44:03

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 5'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:04:04', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1484888e-a49d-401c-aafe-e3f41f6c7982' User entered 'None (0)'	System	18 Oct 2020 23:04:27
	System	18 Oct 2020 23:04:27

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:04:07', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1484888e-a49d-401c-aafe-e3f41f6c7982' User entered 'None (0)'	System	18 Oct 2020 23:04:27
	System	18 Oct 2020 23:04:27

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:04:09', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1484888e-a49d-401c-aafe-e3f41f6c7982' User entered 'None (0)'	System	18 Oct 2020 23:04:27
	System	18 Oct 2020 23:04:27

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:04:12', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1484888e-a49d-401c-aafe-e3f41f6c7982' User entered 'None (0)'	System	18 Oct 2020 23:04:27
	System	18 Oct 2020 23:04:27

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:04:15', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1484888e-a49d-401c-aafe-e3f41f6c7982' User entered 'None (0)'	System	18 Oct 2020 23:04:27
	System	18 Oct 2020 23:04:27

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:04:18', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1484888e-a49d-401c-aafe-e3f41f6c7982' User entered 'None (0)'	System	18 Oct 2020 23:04:27
	System	18 Oct 2020 23:04:27

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:04:22', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1484888e-a49d-401c-aafe-e3f41f6c7982' User entered 'No (N)'	System	18 Oct 2020 23:04:27
	System	18 Oct 2020 23:04:27

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-18T19:04:25', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1484888e-a49d-401c-aafe-e3f41f6c7982' User entered '18 Oct 2020 19:04'	System	18 Oct 2020 23:04:27
	System	18 Oct 2020 23:04:27

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 6'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:27:23', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '78e16258-33dc-47a9-b39f-c1c0ecf1f51c' User entered 'None (0)'	System	20 Oct 2020 00:27:50
	System	20 Oct 2020 00:27:50

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:27:27', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '78e16258-33dc-47a9-b39f-c1c0ecf1f51c' User entered 'None (0)'	System	20 Oct 2020 00:27:50
	System	20 Oct 2020 00:27:50

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:27:31', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '78e16258-33dc-47a9-b39f-c1c0ecf1f51c' User entered 'None (0)'	System	20 Oct 2020 00:27:50
	System	20 Oct 2020 00:27:50

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:27:35', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '78e16258-33dc-47a9-b39f-c1c0ecf1f51c' User entered 'None (0)'	System	20 Oct 2020 00:27:50
	System	20 Oct 2020 00:27:50

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:27:38', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '78e16258-33dc-47a9-b39f-c1c0ecf1f51c' User entered 'None (0)'	System	20 Oct 2020 00:27:50
	System	20 Oct 2020 00:27:50

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:27:41', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '78e16258-33dc-47a9-b39f-c1c0ecf1f51c' User entered 'None (0)'	System	20 Oct 2020 00:27:50
	System	20 Oct 2020 00:27:50

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:27:44', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '78e16258-33dc-47a9-b39f-c1c0ecf1f51c' User entered 'No (N)'	System	20 Oct 2020 00:27:50
	System	20 Oct 2020 00:27:50

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-19T20:27:46', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '78e16258-33dc-47a9-b39f-c1c0ecf1f51c' User entered '19 Oct 2020 20:27'	System	20 Oct 2020 00:27:50
	System	20 Oct 2020 00:27:50

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Oct 2020 21:25:53
User entered 'Day 7'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:57:13', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e77e5480-3832-4abe-ba86-250d67d7a835' User entered 'None (0)'	System	20 Oct 2020 22:57:37
	System	20 Oct 2020 22:57:37

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:57:16', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e77e5480-3832-4abe-ba86-250d67d7a835' User entered 'None (0)'	System	20 Oct 2020 22:57:37
	System	20 Oct 2020 22:57:37

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:57:18', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e77e5480-3832-4abe-ba86-250d67d7a835' User entered 'None (0)'	System	20 Oct 2020 22:57:37
	System	20 Oct 2020 22:57:37

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:57:20', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e77e5480-3832-4abe-ba86-250d67d7a835' User entered 'None (0)'	System	20 Oct 2020 22:57:37
	System	20 Oct 2020 22:57:37

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:57:23', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e77e5480-3832-4abe-ba86-250d67d7a835' User entered 'None (0)'	System	20 Oct 2020 22:57:37
	System	20 Oct 2020 22:57:37

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:57:25', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e77e5480-3832-4abe-ba86-250d67d7a835' User entered 'None (0)'	System	20 Oct 2020 22:57:37
	System	20 Oct 2020 22:57:37

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:57:28', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e77e5480-3832-4abe-ba86-250d67d7a835' User entered 'No (N)'	System	20 Oct 2020 22:57:37
	System	20 Oct 2020 22:57:37

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-10-20T18:57:31', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e77e5480-3832-4abe-ba86-250d67d7a835' User entered '20 Oct 2020 18:57'	System	20 Oct 2020 22:57:37
	System	20 Oct 2020 22:57:37

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 21:25:53

US3432497

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 21:25:53

US3432497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:26
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	27 Oct 2020 18:13:05

US3432497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:26
User entered '22 Oct 2020'	Phoebe Cunningham (b) (4)	27 Oct 2020 18:13:05

US3432497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:26
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	27 Oct 2020 18:13:05

US3432497

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:26
User entered empty.	Phoebe Cunningham (b) (4)	27 Oct 2020 18:13:05

US3432497

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:43
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	28 Oct 2020 12:47:18

US3432497

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'I'	System	28 Oct 2020 12:47:18

US3432497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:46
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	28 Oct 2020 13:10:20

US3432497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:46
User entered '28 Oct 2020'	Kathleen Garvey (b) (4)	28 Oct 2020 13:10:20

US3432497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:46
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	28 Oct 2020 13:10:20

US3432497

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:46
User entered empty.	Kathleen Garvey (b) (4)	28 Oct 2020 13:10:20

US3432497

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:54
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	28 Oct 2020 13:10:23

US3432497

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'I'	System	28 Oct 2020 13:10:23

US3432497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:57
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	04 Nov 2020 13:42:12

US3432497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:57
User entered '4 Nov 2020'	Kathleen Garvey (b) (4)	04 Nov 2020 13:42:12

US3432497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:57
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	04 Nov 2020 13:42:12

US3432497

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:43:57
User entered empty.	Kathleen Garvey (b) (4)	04 Nov 2020 13:42:12

US3432497

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:44:00
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	04 Nov 2020 13:42:16

US3432497

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'I'	System	04 Nov 2020 13:42:16

US3432497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 15:10:18

US3432497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:42
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 15:10:18

US3432497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Nov 2020 15:10:18

US3432497

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'VISIT3'	System	12 Nov 2020 15:10:18

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:02
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:02
User entered '9:15'	(b) (4), (b) (6)	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered '12 Nov 2020 9:15'	System	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:02
User entered '97.8' F	(b) (4), (b) (6)	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:02
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:02
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:02
User entered '78'	(b) (4), (b) (6)	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'bpm'	System	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:02
User entered '16'	(b) (4), (b) (6)	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'breaths/min'	System	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:02
User entered '137'	(b) (4), (b) (6)	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'mmHg'	System	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:02
User entered '86'	(b) (4), (b) (6)	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'mmHg'	System	12 Nov 2020 15:14:38

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42

US3432497

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42

US3432497

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:06
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 15:15:07

US3432497

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:06
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 15:15:07

US3432497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 15:15:19

US3432497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:11
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 15:15:19

US3432497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:11
User entered '9:49'	(b) (4), (b) (6)	12 Nov 2020 15:15:19

US3432497

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered '12 Nov 2020 9:49'	System	12 Nov 2020 15:15:19

US3432497

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:47:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 15:15:24

US3432497

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'I'	System	12 Nov 2020 15:15:24

US3432497

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered 'Day 64'	System	14 Sep 2020 12:57:23

US3432497

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-11-17T19:01:44', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '212a378b-52c6-40a3-b6f4-ad3fd1daa7c1' User entered 'No (N)'	System	18 Nov 2020 00:02:01
	System	18 Nov 2020 00:02:01

US3432497

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-11-17T19:01:50', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '212a378b-52c6-40a3-b6f4-ad3fd1daa7c1' User entered 'No (N)'	System	18 Nov 2020 00:02:01
	System	18 Nov 2020 00:02:01

US3432497

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-11-17T19:01:58', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '212a378b-52c6-40a3-b6f4-ad3fd1daa7c1' User entered '17 Nov 2020 19:01:58'	System	18 Nov 2020 00:02:01
	System	18 Nov 2020 00:02:01

US3432497

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered '14 Nov 2020 00:01'	System	14 Sep 2020 12:57:23

US3432497

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:37:46
Data entry locked.	System	14 Sep 2020 12:57:23
User entered '18 Nov 2020 23:59'	System	14 Sep 2020 12:57:23

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-11-21T15:28:30', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '6979cd48-687e-4ce7-a537-d2039a89206e' User entered 'No (N)'	System	21 Nov 2020 20:28:47

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-11-21T15:28:36', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '6979cd48-687e-4ce7-a537-d2039a89206e' User entered 'No (N)'	System	21 Nov 2020 20:28:47

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-11-21T15:28:44', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '6979cd48-687e-4ce7-a537-d2039a89206e' User entered '21 Nov 2020 15:28:44'	System	21 Nov 2020 20:28:47
	System	21 Nov 2020 20:28:47

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-11-27T17:06:32', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '24ff5ac0-9c41-4183-95b2-b14892767d60'	System	27 Nov 2020 22:06:48
User entered 'No (N)'	System	27 Nov 2020 22:06:48

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-11-27T17:06:38', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '24ff5ac0-9c41-4183-95b2-b14892767d60' User entered 'No (N)'	System	27 Nov 2020 22:06:48

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-11-27T17:06:45', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '24ff5ac0-9c41-4183-95b2-b14892767d60' User entered '27 Nov 2020 17:06:45'	System	27 Nov 2020 22:06:48
	System	27 Nov 2020 22:06:48

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-12-02T07:24:24', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '41e2a619-2bc3-4f02-ad00-10e71df6f813'	System	02 Dec 2020 12:24:42
User entered 'No (N)'	System	02 Dec 2020 12:24:42

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-12-02T07:24:32', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '41e2a619-2bc3-4f02-ad00-10e71df6f813'	System	02 Dec 2020 12:24:42
User entered 'No (N)'	System	02 Dec 2020 12:24:42

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-12-02T07:24:40', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '41e2a619-2bc3-4f02-ad00-10e71df6f813' User entered '02 Dec 2020 07:24:40'	System	02 Dec 2020 12:24:42
	System	02 Dec 2020 12:24:42

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-12-11T14:15:04', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '11fc2c1a-07d4-40c1-8757-2c4ffefcee51'	System	11 Dec 2020 19:15:22
User entered 'No (N)'	System	11 Dec 2020 19:15:22

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-12-11T14:15:11', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '11fc2c1a-07d4-40c1-8757-2c4ffefcee51'	System	11 Dec 2020 19:15:22
User entered 'No (N)'	System	11 Dec 2020 19:15:22

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-12-11T14:15:20', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '11fc2c1a-07d4-40c1-8757-2c4ffefcee51' User entered '11 Dec 2020 14:15:20'	System	11 Dec 2020 19:15:22
	System	11 Dec 2020 19:15:22

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-12-16T08:13:47', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '459060db-f403-458d-a1fa-e2a827b63d83'	System	16 Dec 2020 13:14:06
User entered 'No (N)'	System	16 Dec 2020 13:14:06

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-12-16T08:13:57', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '459060db-f403-458d-a1fa-e2a827b63d83'	System	16 Dec 2020 13:14:06
User entered 'No (N)'	System	16 Dec 2020 13:14:06

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-12-16T08:14:03', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '459060db-f403-458d-a1fa-e2a827b63d83' User entered '16 Dec 2020 08:14:03'	System	16 Dec 2020 13:14:06
	System	16 Dec 2020 13:14:06

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-12-23T07:50:08', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'd681b874-827d-49d9-8861-26b222ad6ffd' User entered 'No (N)'	System	23 Dec 2020 12:50:44
	System	23 Dec 2020 12:50:44

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-12-23T07:50:36', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'd681b874-827d-49d9-8861-26b222ad6ffd' User entered 'No (N)'	System	23 Dec 2020 12:50:44
	System	23 Dec 2020 12:50:44

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2020-12-23T07:50:41', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'd681b874-827d-49d9-8861-26b222ad6ffd' User entered '23 Dec 2020 07:50:41'	System	23 Dec 2020 12:50:44
	System	23 Dec 2020 12:50:44

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-01T12:02:22', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c482aa7d-c546-4332-9ca6-79a5335425b5'	System	01 Jan 2021 17:02:38
User entered 'No (N)'	System	01 Jan 2021 17:02:38

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-01T12:02:27', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c482aa7d-c546-4332-9ca6-79a5335425b5'	System	01 Jan 2021 17:02:38
User entered 'No (N)'	System	01 Jan 2021 17:02:38

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-01T12:02:34', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c482aa7d-c546-4332-9ca6-79a5335425b5' User entered '01 Jan 2021 12:02:34'	System	01 Jan 2021 17:02:38
	System	01 Jan 2021 17:02:38

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-08T20:54:20', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c72ef01c-f4d7-480c-a4f2-82e4c98678e4' User entered 'No (N)'	System	09 Jan 2021 01:54:40
	System	09 Jan 2021 01:54:40

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-08T20:54:33', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c72ef01c-f4d7-480c-a4f2-82e4c98678e4' User entered 'No (N)'	System	09 Jan 2021 01:54:40
	System	09 Jan 2021 01:54:40

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-08T20:54:37', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c72ef01c-f4d7-480c-a4f2-82e4c98678e4' User entered '08 Jan 2021 20:54:37'	System	09 Jan 2021 01:54:40

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-15T12:06:53', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '4d315d3a-ea66-4e29-8bd2-b5d2745a4c86'	System	15 Jan 2021 17:07:17
User entered 'No (N)'	System	15 Jan 2021 17:07:17

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-15T12:07:04', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '4d315d3a-ea66-4e29-8bd2-b5d2745a4c86'	System	15 Jan 2021 17:07:17
User entered 'No (N)'	System	15 Jan 2021 17:07:17

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-15T12:07:09', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '4d315d3a-ea66-4e29-8bd2-b5d2745a4c86' User entered '15 Jan 2021 12:07:09'	System	15 Jan 2021 17:07:17
	System	15 Jan 2021 17:07:17

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-20T08:44:59', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'a5eb88fe-e586-401b-a494-93e18a6fe85e'	System	20 Jan 2021 13:45:23
User entered 'No (N)'	System	20 Jan 2021 13:45:23

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-20T08:45:02', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'a5eb88fe-e586-401b-a494-93e18a6fe85e' User entered 'No (N)'	System	20 Jan 2021 13:45:23

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-20T08:45:20', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'a5eb88fe-e586-401b-a494-93e18a6fe85e' User entered '20 Jan 2021 08:45:20'	System	20 Jan 2021 13:45:23
	System	20 Jan 2021 13:45:23

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-27T09:09:50', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '7a788ddb-0c66-41f2-b468-62ae93639e89' User entered 'No (N)'	System	27 Jan 2021 14:10:03
	System	27 Jan 2021 14:10:03

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-27T09:09:54', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '7a788ddb-0c66-41f2-b468-62ae93639e89' User entered 'No (N)'	System	27 Jan 2021 14:10:03
	System	27 Jan 2021 14:10:03

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-01-27T09:09:58', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '7a788ddb-0c66-41f2-b468-62ae93639e89' User entered '27 Jan 2021 09:09:58'	System	27 Jan 2021 14:10:03
	System	27 Jan 2021 14:10:03

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-02-05T13:43:45', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'a4721eea-df63-4540-9214-159cba43817f' User entered 'No (N)'	System	05 Feb 2021 18:43:55
	System	05 Feb 2021 18:43:55

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-02-05T13:43:47', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'a4721eea-df63-4540-9214-159cba43817f' User entered 'No (N)'	System	05 Feb 2021 18:43:55
	System	05 Feb 2021 18:43:55

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-02-05T13:43:52', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'a4721eea-df63-4540-9214-159cba43817f' User entered '05 Feb 2021 13:43:52'	System	05 Feb 2021 18:43:55
	System	05 Feb 2021 18:43:55

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-02-10T05:33:14', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '3302d8cc-f235-4a4b-8275-b044fef564f0'	System	10 Feb 2021 10:33:23
User entered 'No (N)'	System	10 Feb 2021 10:33:23

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-02-10T05:33:16', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '3302d8cc-f235-4a4b-8275-b044fef564f0'	System	10 Feb 2021 10:33:23
User entered 'No (N)'	System	10 Feb 2021 10:33:23

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-02-10T05:33:20', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '3302d8cc-f235-4a4b-8275-b044fef564f0' User entered '10 Feb 2021 05:33:20'	System	10 Feb 2021 10:33:23
	System	10 Feb 2021 10:33:23

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-02-21T08:12:28', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '97083d23-1d67-4ed5-a425-2652887a3874' User entered 'No (N)'	System	21 Feb 2021 13:12:38
	System	21 Feb 2021 13:12:38

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-02-21T08:12:31', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '97083d23-1d67-4ed5-a425-2652887a3874' User entered 'No (N)'	System	21 Feb 2021 13:12:38
	System	21 Feb 2021 13:12:38

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-02-21T08:12:34', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '97083d23-1d67-4ed5-a425-2652887a3874'	System	21 Feb 2021 13:12:38
User entered '21 Feb 2021 08:12:34'	System	21 Feb 2021 13:12:38

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-02-24T07:00:10-05:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f4bdad2e-82a4-4fad-83d6-cafc488c2cc8' User entered 'No (N)'	System	24 Feb 2021 12:00:20
	System	24 Feb 2021 12:00:20

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-02-24T07:00:13-05:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f4bdad2e-82a4-4fad-83d6-cafc488c2cc8' User entered 'No (N)'	System	24 Feb 2021 12:00:20

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-02-24T07:00:16-05:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'f4bdad2e-82a4-4fad-83d6-cafc488c2cc8' User entered '24 Feb 2021 12:00:16'	System	24 Feb 2021 12:00:20
	System	24 Feb 2021 12:00:20

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-03T09:27:55-05:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1e17495d-ce3e-4740-928f-ae3753fdb252'	System	03 Mar 2021 14:28:06
User entered 'No (N)'	System	03 Mar 2021 14:28:06

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-03T09:27:59-05:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1e17495d-ce3e-4740-928f-ae3753fdb252'	System	03 Mar 2021 14:28:06
User entered 'No (N)'	System	03 Mar 2021 14:28:06

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-03T09:28:02-05:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '1e17495d-ce3e-4740-928f-ae3753fdb252'	System	03 Mar 2021 14:28:06
User entered '03 Mar 2021 09:28:02'	System	03 Mar 2021 14:28:06

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-11T09:21:55-05:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e085fd2c-21ec-4427-b2ff-9756c8e976ba'	System	11 Mar 2021 14:22:11
User entered 'No (N)'	System	11 Mar 2021 14:22:11

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-11T09:21:58-05:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e085fd2c-21ec-4427-b2ff-9756c8e976ba'	System	11 Mar 2021 14:22:11
User entered 'No (N)'	System	11 Mar 2021 14:22:11

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-11T09:22:01-05:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'e085fd2c-21ec-4427-b2ff-9756c8e976ba' User entered '11 Mar 2021 09:22:01'	System	11 Mar 2021 14:22:11
	System	11 Mar 2021 14:22:11

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-17T07:43:29-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c2d72260-35a0-409b-8da1-d4592100c3af'	System	17 Mar 2021 11:43:39
User entered 'No (N)'	System	17 Mar 2021 11:43:39

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-17T07:43:33-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c2d72260-35a0-409b-8da1-d4592100c3af'	System	17 Mar 2021 11:43:39
User entered 'No (N)'	System	17 Mar 2021 11:43:39

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-17T07:43:36-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c2d72260-35a0-409b-8da1-d4592100c3af' User entered '17 Mar 2021 07:43:36'	System	17 Mar 2021 11:43:39
	System	17 Mar 2021 11:43:39

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-24T05:53:41-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c09c041f-034d-4ac2-a87e-eeacba4304db'	System	24 Mar 2021 09:53:51
User entered 'No (N)'	System	24 Mar 2021 09:53:51

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-24T05:53:45-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c09c041f-034d-4ac2-a87e-eeacba4304db'	System	24 Mar 2021 09:53:51
User entered 'No (N)'	System	24 Mar 2021 09:53:51

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-24T05:53:48-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'c09c041f-034d-4ac2-a87e-eeacba4304db' User entered '24 Mar 2021 05:53:48'	System	24 Mar 2021 09:53:51

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-31T07:13:19-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '3c24fad9-9bc4-4a33-b3e7-55a965dae962'	System	31 Mar 2021 11:13:30
User entered 'No (N)'	System	31 Mar 2021 11:13:30

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-31T07:13:23-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '3c24fad9-9bc4-4a33-b3e7-55a965dae962'	System	31 Mar 2021 11:13:30
User entered 'No (N)'	System	31 Mar 2021 11:13:30

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-31T07:13:26-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '3c24fad9-9bc4-4a33-b3e7-55a965dae962'	System	31 Mar 2021 11:13:30
User entered '31 Mar 2021 07:13:26'	System	31 Mar 2021 11:13:30

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-04-07T07:03:17-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'ef2b6ee5-6149-4fb8-9017-7680298a433e' User entered 'No (N)'	System	07 Apr 2021 11:03:28
	System	07 Apr 2021 11:03:28

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-04-07T07:03:20-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'ef2b6ee5-6149-4fb8-9017-7680298a433e' User entered 'No (N)'	System	07 Apr 2021 11:03:28

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-04-07T07:03:23-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'ef2b6ee5-6149-4fb8-9017-7680298a433e'	System	07 Apr 2021 11:03:28
User entered '07 Apr 2021 07:03:23'	System	07 Apr 2021 11:03:28

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-04-18T11:59:34-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '09f9ebc1-a3e9-4cca-8497-82752a437567'	System	18 Apr 2021 16:00:24
User entered 'Yes (Y)'	System	18 Apr 2021 16:00:24

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Have you been exposed to someone with 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-04-18T11:59:32-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '09f9ebc1-a3e9-4cca-8497-82752a437567'	System	18 Apr 2021 16:00:24
User entered 'No (N)'	System	18 Apr 2021 16:00:24

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-04-18T11:59:29-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '09f9ebc1-a3e9-4cca-8497-82752a437567' User entered 'No (N)'	System	18 Apr 2021 16:00:24

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-04-18T11:59:27-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '09f9ebc1-a3e9-4cca-8497-82752a437567'	System	18 Apr 2021 16:00:24
User entered 'Yes (Y)'	System	18 Apr 2021 16:00:24

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

Please 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 (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-04-18T11:59:23-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '09f9ebc1-a3e9-4cca-8497-82752a437567'	System	18 Apr 2021 16:00:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Apr 2021 16:00:24

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-04-18T11:59:49-04:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: '09f9ebc1-a3e9-4cca-8497-82752a437567'	System	18 Apr 2021 16:00:24
User entered '18 Apr 2021 11:59:49'	System	18 Apr 2021 16:00:24

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 08:10:19

US3432497

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:10:19
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 08:10:19

US3432497

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:39:14

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 05:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-03T09:28:13-05:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'bbee9690-50b4-4210-83ff-9a4343c61e17'	System	03 Mar 2021 14:28:23
User entered 'No (N)'	System	03 Mar 2021 14:28:23

US3432497

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:39:14

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F9B77E17-47D8-4659-B528-8E28D0FD8F32)', Time: '2021-03-03T09:28:20-05:00', User OID: 'PatientReportedOutcome (US3432497)', ODM File OID: 'bbee9690-50b4-4210-83ff-9a4343c61e17'	System	03 Mar 2021 14:28:23
User entered '03 Mar 2021 09:28:20'	System	03 Mar 2021 14:28:23

US3432497

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:30:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 14:20:41

US3432497

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:30:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '7 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 14:20:41

US3432497

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:30:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Dec 2020 14:20:41

US3432497

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:30:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 14:20:41

US3432497

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:30:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 14:21:32

US3432497

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:45:42
User entered 'I'	System	07 Dec 2020 14:21:32

US3432497

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:30:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Jan 2021 15:04:35

US3432497

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:30:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '12 Jan 2021'	(b) (4), (b) (6)	12 Jan 2021 15:04:35

US3432497

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:30:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Jan 2021 15:04:35

US3432497

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:30:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 15:04:35

US3432497

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:30:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Jan 2021 15:04:44

US3432497

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
User entered 'I'	System	12 Jan 2021 15:04:44

US3432497

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:56:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Yes (Y)'	Bethany Evans (b) (4)	11 Feb 2021 19:39:57

US3432497

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:56:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '11 Feb 2021'	Bethany Evans (b) (4)	11 Feb 2021 19:39:57

US3432497

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:56:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Contact Made (CONTACT MADE)'	Bethany Evans (b) (4)	11 Feb 2021 19:39:57

US3432497

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:56:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered empty.	Bethany Evans (b) (4)	11 Feb 2021 19:39:57

US3432497

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:57:00
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Yes (Y)'	Bethany Evans (b) (4)	11 Feb 2021 19:40:02

US3432497

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
User entered 'I'	System	11 Feb 2021 19:40:02

US3432497

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:57:05
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	15 Mar 2021 15:21:25

US3432497

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:57:05
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered '15 Mar 2021'	Tenaizus Woods (b) (4)	15 Mar 2021 15:21:25

US3432497

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:57:05
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4)	15 Mar 2021 15:21:25

US3432497

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:57:05
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered empty.	Tenaizus Woods (b) (4)	15 Mar 2021 15:21:25

US3432497

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:57:09
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	15 Mar 2021 15:21:30

US3432497

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:23:30
User entered 'I'	System	15 Mar 2021 15:21:30

US3432497

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:59:13
User entered 'Yes (Y)'	Bethany Evans (b) (4)	05 Apr 2021 16:41:09
	(b) (4)	

US3432497

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:59:13
User entered '05 Apr 2021'	Bethany Evans (b) (4)	05 Apr 2021 16:41:09
	(b) (4)	

US3432497

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:59:13
User entered 'Clinic (Clinic)'	Bethany Evans (b) (4)	05 Apr 2021 16:41:09
	(b) (4)	

US3432497

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	05 Apr 2021 16:41:09

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 13:59:44
User entered 'Yes (Y)'	Bethany Evans (b) (4) (b) (4)	05 Apr 2021 16:41:58

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 13:59:44
User entered '05 Apr 2021'	Bethany Evans (b) (4) (b) (4)	05 Apr 2021 16:41:58

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 13:59:44
User entered '11:45'	Bethany Evans (b) (4) (b) (4)	05 Apr 2021 16:41:58

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
User entered '05 Apr 2021 11:45'	System	05 Apr 2021 16:41:58

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:59:44
User entered '37.0' C	Bethany Evans (b) (4)	05 Apr 2021 16:41:58
	(b) (4)	

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 13:59:44
User entered 'Oral (Oral)'	Bethany Evans (b) (4) (b) (4)	05 Apr 2021 16:41:58

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 13:59:44
User entered empty.	Bethany Evans (b) (4) (b) (4)	05 Apr 2021 16:41:58

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:59:44
User entered '080'	Bethany Evans (b) (4)	05 Apr 2021 16:41:58
	(b) (4)	

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 16:41:58

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 13:59:44
User entered '015'	Bethany Evans (b) (4) (b) (4)	05 Apr 2021 16:41:58

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 16:41:58

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:59:44
User entered '120'	Bethany Evans (b) (4)	05 Apr 2021 16:41:58
	(b) (4)	

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 16:41:58

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 13:59:44
User entered '073'	Bethany Evans (b) (4) (b) (4)	05 Apr 2021 16:41:58

US3432497

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 16:41:58

US3432497

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:59:50
User entered 'No (N)'	Bethany Evans (b) (4)	05 Apr 2021 16:42:04
	(b) (4)	

US3432497

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:59:50
User entered empty.	Bethany Evans (b) (4)	05 Apr 2021 16:42:04
	(b) (4)	

US3432497

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:59:57
User entered 'Yes (Y)'	Bethany Evans (b) (4)	05 Apr 2021 16:57:46
	(b) (4)	

US3432497

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 13:59:57
User entered '05 Apr 2021'	Bethany Evans (b) (4) (b) (4)	05 Apr 2021 16:57:46

US3432497

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:59:57
User entered '12:00'	Bethany Evans (b) (4)	05 Apr 2021 16:57:46
	(b) (4)	

US3432497

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
User entered '05 Apr 2021 12:00'	System	05 Apr 2021 16:57:46

US3432497

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:41
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 14:00:01
User entered 'Yes (Y)'	Bethany Evans (b) (4) (b) (4)	05 Apr 2021 16:42:08

US3432497

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:14

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 16:42:08

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:39:14

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:34
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 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 Mar 2021 04:34:07
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 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 in EDC' (Site from DM).	Xhoi Mitre (b) (4)	09 Mar 2021 19:57:20
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:57
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 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 08:27:36
User entered '5 Oct 2020'	Xhoi Mitre (b) (4)	06 Oct 2020 15:54:06

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:39:14

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:34
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:57
User entered '12:45'	Xhoi Mitre (b) (4)	06 Oct 2020 15:54:06

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:39:14

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:34
User entered '5 Oct 2020 12:45'	System	06 Oct 2020 15:54:06

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:39:14

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:34
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:57
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:54:06

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:39:14

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:34
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:14:57
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:54:06

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered 'Day 1 (Day 1)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '01 Oct 2020'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '0'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User entered '%'	System	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:50:37
User closed query 'Per source "None" please check & edit' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 22:50:35
Query 'Per source "None" please check & edit' answered by data change (Site from CRA).	System	09 Mar 2021 19:58:30
User entered 'None (None)' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	09 Mar 2021 19:58:30
User opened query 'Per source "None" please check & edit' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:16:04
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:36
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:39:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:16

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered 'Day 2 (Day 2)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '02 Oct 2020'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '0'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User entered '%'	System	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:39:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:56:58

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered 'Day 3 (Day 3)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '03 Oct 2020'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '0'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User entered '%'	System	06 Oct 2020 15:57:25

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:49:28
User closed query 'Response does not clarify if congestion was mild or moderate, please clarify' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 16:49:25
Query 'Response does not clarify if congestion was mild or moderate, please clarify' answered with 'Nasal congestion is mild, confirmed in source' (Site from CRA).	Austin Kim (b) (4)	19 Mar 2021 14:25:57
User opened query 'Response does not clarify if congestion was mild or moderate, please clarify' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 02:52:50
User closed query 'Per source safety call Day 22 (05Oct20) subject had Moderate runny nose and sneezing. Nasal congestion not mentioned. Please check and edit.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 02:51:30
Query 'Per source safety call Day 22 (05Oct20) subject had Moderate runny nose and sneezing. Nasal congestion not mentioned. Please check and edit.' answered with 'moderate nasal congestion confirmed per illness visit on 05oct2020 where pt reported mild nasal congestion 03oct2020' (Site from CRA).	Austin Kim (b) (4)	15 Mar 2021 16:03:08
User opened query 'Per source safety call Day 22 (05Oct20) subject had Moderate runny nose and sneezing. Nasal congestion not mentioned. Please check and edit.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:20:34
Query 'Per source safety call Day 22 (05Oct20) subject had Moderate runny nose and sneezing. Please check and edit.' canceled (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:17:40
User opened query 'Per source safety call Day 22 (05Oct20) subject had Moderate runny nose and sneezing. Please check and edit.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:17:26
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 02:51:38
User closed query 'Per source safety call Day 22 (05Oct20) subject had Moderate runny nose and sneezing. Please check and edit.' (Site from CRA). Query 'Per source safety call Day 22 (05Oct20) subject had Moderate runny nose and sneezing. Please check and edit.' answered with 'updated to moderate per safety call 05oct2020' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 02:51:36
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Austin Kim (b) (4)	15 Mar 2021 16:02:15
User opened query 'Per source safety call Day 22 (05Oct20) subject had Moderate runny nose and sneezing. Please check and edit.' (Site from CRA).	(b) (4)	15 Mar 2021 16:02:03
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 17:17:43
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:17:34
User entered 'None (None)'	(b) (4)	03 Dec 2020 17:15:24
	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25
	(b) (4)	

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:39:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 15:57:25

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered 'Day 4 (Day 4)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '4 Oct 2020'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '0'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User entered '%'	System	06 Oct 2020 16:00:21

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 02:53:11
User closed query 'Per source safety call Day 22 (05Oct20) subject had Moderate cough, congestion & runny nose . Please check and edit.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 02:53:09
Query 'Per source safety call Day 22 (05Oct20) subject had Moderate cough, congestion & runny nose . Please check and edit.' answered with 'updated to moderate per safety call 05oct2020' (Site from CRA).	Austin Kim (b) (4)	15 Mar 2021 16:04:31
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	15 Mar 2021 16:03:53
User opened query 'Per source safety call Day 22 (05Oct20) subject had Moderate cough, congestion & runny nose . Please check and edit.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 17:21:07
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 02:53:19
User closed query 'Per source safety call Day 22 (05Oct20) subject had Moderate cough, congestion & runny nose . Please check and edit.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 02:53:17
Query 'Per source safety call Day 22 (05Oct20) subject had Moderate cough, congestion & runny nose . Please check and edit.' answered with 'updated to moderate per safety call 05oct2020' (Site from CRA).	Austin Kim (b) (4)	15 Mar 2021 16:04:34
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	15 Mar 2021 16:03:53
User opened query 'Per source safety call Day 22 (05Oct20) subject had Moderate cough, congestion & runny nose . Please check and edit.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:22:17
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 17:22:10
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 02:53:23
User closed query 'Per source safety call Day 22 (05Oct20) subject had Moderate cough, congestion & runny nose . Please check and edit.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 02:53:21
Query 'Per source safety call Day 22 (05Oct20) subject had Moderate cough, congestion & runny nose . Please check and edit.' answered with 'updated to moderate per safety call 05oct2020' (Site from CRA).	Austin Kim (b) (4)	15 Mar 2021 16:04:37
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	15 Mar 2021 16:03:53
User opened query 'Per source safety call Day 22 (05Oct20) subject had Moderate cough, congestion & runny nose . Please check and edit.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:22:25
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 17:22:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:39:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:00:21

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered 'Day 5 (Day 5)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '5 Oct 2020'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '0'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '99'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User entered '%'	System	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '37.5' C	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:39:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	06 Oct 2020 16:01:31

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered 'Day 6 (Day 6)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '06 Oct 2020'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '0'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '97'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User entered '%'	System	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '97.8' F	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'Mild (Mild)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:39:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:43:54

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered 'Day 7 (Day 7)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '07 Oct 2020'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '0'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '98'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User entered '%'	System	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '97.2' F	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:39:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:18

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered 'Day 8 (Day 8)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '08 Oct 2020'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '0'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '100'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User entered '%'	System	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '96.5' F	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:39:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:44:43

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered 'Day 9 (Day 9)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '09 Oct 2020'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '0'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '99'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User entered '%'	System	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered '98.0' F	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:39:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:24
User entered 'None (None)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:09

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:39:14

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:51
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:10
User entered '5 Oct 2020'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:41

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:39:14

[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 09:15:51
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 05 OCT 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)	05 Mar 2021 08:47:53
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 05 OCT 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)	04 Mar 2021 17:29:48
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:10
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 05 OCT 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 05:17:48
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:41

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:39:14

[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 09:15:51
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:10
User entered 'No (N)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:41

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:39:14

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:51
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User closed query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 08:54:19
Query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'updated' (Site from DM).	Austin Kim (b) (4)	04 Mar 2021 17:29:54
User opened query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 21:06:13
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:10
User entered '5 Oct 2020'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:41

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:39:14

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:51
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:10
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:41

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:39:14

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:51
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:10
User entered empty.	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:41

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:39:14

[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 09:15:51
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:10
User entered 'No (N)'	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:41

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:39:14

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:51
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:10
User entered empty.	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:41

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:39:14

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:51
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:15:10
User entered empty.	Xhoi Mitre (b) (4)	09 Oct 2020 23:45:41

US3432497

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:39:14

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:51
User entered '0'	System	09 Oct 2020 23:45:41

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:39:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Austin Kim (b) (4) (b) (4)	04 Mar 2021 17:31:24

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:39:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:11:44
User entered 'Yes (Y)'	Austin Kim (b) (4)	04 Mar 2021 17:31:24
	(b) (4)	

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:39:14

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:38:05
User closed query 'Per source should be 7-Oct-20. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:38:03
Query 'Per source should be 7-Oct-20. Please verify and update. ' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Apr 2021 15:03:11
	(b) (4)	
User entered '07 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Apr 2021 14:57:29
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:11:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:11:48
	(b) (4), (b) (6)	
User opened query 'Per source should be 7-Oct-20. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 20:11:40
	(b) (4)	
User entered '08 Oct 2020'	Austin Kim (b) (4)	04 Mar 2021 17:31:24
	(b) (4)	

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:39:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Austin Kim (b) (4) (b) (4)	04 Mar 2021 17:31:24

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:39:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:11:48
User entered 'Yes (Y)'	Austin Kim (b) (4)	04 Mar 2021 17:31:24
	(b) (4)	

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:39:14

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
	(b) (4), (b) (6)	14 Apr 2021 20:11:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 07:52:53
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is reported under COVID PCR Saliva Day 3 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	Jun Bai Park Chang (b) (4)	07 Apr 2021 21:39:36
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is reported under COVID PCR Saliva Day 3 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' answered with 'Please note both of them were collected the same date by pt' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:08:45
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is reported under COVID PCR Saliva Day 3 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	Austin Kim (b) (4)	04 Mar 2021 17:31:24
User entered '08 Oct 2020'	(b) (4)	

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:39:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Austin Kim (b) (4) (b) (4)	04 Mar 2021 17:31:24

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:39:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Apr 2021 20:11:48
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4) (b) (4)	04 Mar 2021 17:31:24

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:39:14

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Apr 2021 20:11:48
User entered empty.	Austin Kim (b) (4) (b) (4)	04 Mar 2021 17:31:24

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:39:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Austin Kim (b) (4) (b) (4)	04 Mar 2021 17:31:24

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:39:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:11:48
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	04 Mar 2021 17:31:24
	(b) (4)	

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:39:14

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:11:48
User entered empty.	Austin Kim (b) (4)	04 Mar 2021 17:31:24
	(b) (4)	

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:39:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Austin Kim (b) (4) (b) (4)	04 Mar 2021 17:31:24

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:39:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:11:48
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	04 Mar 2021 17:31:24
	(b) (4)	

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:39:14

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Apr 2021 20:11:48
User entered empty.	Austin Kim (b) (4) (b) (4)	04 Mar 2021 17:31:24

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:39:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Austin Kim (b) (4) (b) (4)	04 Mar 2021 17:31:24

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:39:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:11:48
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	04 Mar 2021 17:31:24
	(b) (4)	

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:39:14

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:11:48
User entered empty.	Austin Kim (b) (4)	04 Mar 2021 17:31:24
	(b) (4)	

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:39:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Austin Kim (b) (4) (b) (4)	04 Mar 2021 17:31:24

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:39:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:11:48
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	04 Mar 2021 17:31:24
	(b) (4)	

US3432497

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:39:14

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:11:48
User entered empty.	Austin Kim (b) (4)	04 Mar 2021 17:31:24
	(b) (4)	

US3432497

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:06
User entered 'Yes (Y)'	Austin Kim (b) (4)	04 Mar 2021 17:28:58

US3432497

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:06
User entered '05 Oct 2020'	Austin Kim (b) (4)	04 Mar 2021 17:28:58

US3432497

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:06
User entered 'Clinic (Clinic)'	Austin Kim (b) (4)	04 Mar 2021 17:28:58

US3432497

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User entered 'SICKD1'	System	04 Mar 2021 17:28:58

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:27
User entered 'Yes (Y)'	Austin Kim (b) (4)	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:27
User entered '05 Oct 2020'	Austin Kim (b) (4)	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:27
User entered '12:50'	Austin Kim (b) (4)	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User entered '05 Oct 2020 12:50'	System	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:27
User entered missing code ND - Not Done.	Austin Kim (b) (4)	04 Mar 2021 17:29:24
DataPoint set to visible.	(b) (4) System	04 Mar 2021 17:28:58

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:27
User entered missing code ND - Not Done.	Austin Kim (b) (4)	04 Mar 2021 17:29:24
DataPoint set to visible.	(b) (4) System	04 Mar 2021 17:28:58

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:27
User entered '37.5' C	Austin Kim (b) (4)	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:27
User entered 'Oral (Oral)'	Austin Kim (b) (4)	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:27
User entered empty.	Austin Kim (b) (4)	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:27
User entered '82'	Austin Kim (b) (4)	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User entered 'bpm'	System	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:27
User entered '16'	Austin Kim (b) (4)	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User entered 'breaths/min'	System	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:27
User entered '141'	Austin Kim (b) (4)	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User entered 'mmHg'	System	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:27
User entered '87'	Austin Kim (b) (4)	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User entered 'mmHg'	System	04 Mar 2021 17:29:24

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54

US3432497

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54

US3432497

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:32
User entered 'Yes (Y)'	Austin Kim (b) (4)	04 Mar 2021 17:29:33

US3432497

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:32
User entered '05 Oct 2020'	Austin Kim (b) (4)	04 Mar 2021 17:29:33

US3432497

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:39:14

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:43
User entered 'Yes (Y)'	Austin Kim (b) (4)	04 Mar 2021 17:29:39

US3432497

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:39:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:25:54
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:47:43
User entered '05 Oct 2020'	Austin Kim (b) (4)	04 Mar 2021 17:29:39

US3432497

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

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:11:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	25 Jan 2021 18:31:29

US3432497

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

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:11:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '25 Jan 2021'	Bruce Bausk (b) (4)	25 Jan 2021 18:31:29

US3432497

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

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

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 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:11:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4)	25 Jan 2021 18:31:29

US3432497

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

Form: Visit Date

Generated On: 09 Jun 2021 17:39:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 18:31:29

US3432497

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:14

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:12:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '25 Jan 2021'	Bruce Bausk (b) (4)	25 Jan 2021 18:31:44

US3432497

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:14

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:12:01
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 18:29:10
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:58:38

US3432497

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:14

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:12:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	25 Jan 2021 18:31:44

US3432497

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:14

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:12:01
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	19 Mar 2021 18:29:10
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:58:38

US3432497

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:14

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:12:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '25 Jan 2021'	Bruce Bausk (b) (4)	25 Jan 2021 18:31:44

US3432497

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:14

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:12:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'mRNA-1273 (mRNA-1273)'	Bruce Bausk (b) (4)	25 Jan 2021 18:31:44

US3432497

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:14

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:12:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'mRNA-1273 (mRNA-1273)'	Bruce Bausk (b) (4)	25 Jan 2021 18:31:44

US3432497

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:14

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:12:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'mRNA-1273 (mRNA-1273)'	Bruce Bausk (b) (4)	25 Jan 2021 18:31:44

US3432497

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:14

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:12:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'No (N)'	Bruce Bausk (b) (4)	25 Jan 2021 18:31:44

US3432497

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:14

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered empty.	System	25 Jan 2021 18:31:44

US3432497

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:14

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered empty.	System	25 Jan 2021 18:31:44

US3432497

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:26:33
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	25 Jan 2021 18:42:36

US3432497

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:26:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 25Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 25Jan2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'in PPD please just look. 1F60IQS' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 25Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). User entered '25 Jan 2021'	(b) (4), (b) (6)	15 Mar 2021 07:35:17
	Monica Feeley (b) (4)	12 Mar 2021 21:38:20
	(b) (4)	
	(b) (4), (b) (6)	08 Feb 2021 17:09:52
	Bruce Bausk (b) (4)	25 Jan 2021 18:42:36
	(b) (4)	

US3432497

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:52:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
User entered '13:27'	Bruce Bausk (b) (4)	25 Jan 2021 18:42:36

US3432497

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered '25 Jan 2021 13:27'	System	25 Jan 2021 18:42:36

US3432497

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:39:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:52:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	25 Jan 2021 18:42:43

US3432497

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:39:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:52:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '25 Jan 2021'	Bruce Bausk (b) (4)	25 Jan 2021 18:42:43

US3432497

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:39:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:52:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered '13:30'	Bruce Bausk (b) (4)	25 Jan 2021 18:42:43

US3432497

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:34
User entered '25 Jan 2021 13:30'	System	25 Jan 2021 18:42:43

US3432497

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:39:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:58:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:26:29
DataPoint Un-verified.	Xhoi Mitre (b) (4)	20 Apr 2021 21:23:53
Signature has been broken.	Xhoi Mitre (b) (4)	20 Apr 2021 21:23:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	20 Apr 2021 21:23:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:43:04
User entered 'No (N)'	Monica Feeley (b) (4)	03 Mar 2021 16:54:07

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:28:26
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:19
User entered	System	21 Apr 2021 17:03:16
'USA-US078-2021-mRNA-1273-P301000021'		
User entered 'New'	(b) (4), (b) (6)	21 Apr 2021 17:03:16

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:07:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:07:12
Data point term sent to Coder	System	30 Apr 2021 16:00:49
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	30 Apr 2021 16:00:16
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	30 Apr 2021 16:00:16
Signature has been broken.	Monica Feeley (b) (4) (b) (4)	30 Apr 2021 16:00:16
User entered 'BREAST CANCER (L breast)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	30 Apr 2021 16:00:16
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	21 Apr 2021 19:28:26
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:30:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:30:37
Data point term sent to Coder	System	20 Apr 2021 21:29:18
User entered 'Breast Cancer'	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:28:26
User entered '12 Apr 2021'	Xhoi Mitre (b) (4)	20 Apr 2021 21:28:51
	(b) (4)	

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:28:26
User entered empty.	Xhoi Mitre (b) (4)	20 Apr 2021 21:28:51
	(b) (4)	

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:28:26
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	20 Apr 2021 21:28:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 16:39:24
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:28:26
User entered empty.	Xhoi Mitre (b) (4)	20 Apr 2021 21:28:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:28:26
User entered empty.	Xhoi Mitre (b) (4)	20 Apr 2021 21:28:51
	(b) (4)	

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
	(b) (4), (b) (6)	
DataPoint Verified.	Xhoi Mitre (b) (4)	21 Apr 2021 19:28:26
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'		20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:28:26
User entered '0'	Xhoi Mitre (b) (4)	20 Apr 2021 21:28:51
	(b) (4)	

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:28:26
User entered empty.	Xhoi Mitre (b) (4)	20 Apr 2021 21:28:51
	(b) (4)	

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:28:26
	(b) (4)	
User entered '0'	Xhoi Mitre (b) (4)	20 Apr 2021 21:28:51
	(b) (4)	

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered 'I'	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:28:26
User entered 'Not Applicable (NOT APPLICABLE)'	Xhoi Mitre (b) (4)	20 Apr 2021 21:28:51
	(b) (4)	

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:28:26
User entered '0'	Xhoi Mitre (b) (4)	20 Apr 2021 21:28:51
	(b) (4)	

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:39:19
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:32:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:28:26
User entered 'I'	Xhoi Mitre (b) (4)	20 Apr 2021 21:28:51
	(b) (4)	

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 16:39:37
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:28:26
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Xhoi Mitre (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	21 Apr 2021 19:28:26
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm onset date as the subject had mammogram on 18 Mar 2021.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 18:11:46
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)	30 Apr 2021 18:11:39
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)	30 Apr 2021 18:11:36
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 'Biopsy on 08APR2021 indicated invasive ductal carcinoma' (Site from Safety).	Monica Feeley (b) (4)	30 Apr 2021 16:02:46
DataPoint Un-verified.	Monica Feeley (b) (4)	30 Apr 2021 16:02:03
Signature has been broken.	Monica Feeley (b) (4)	30 Apr 2021 16:02:03
User entered 'PARTICIPANT REPORTS RECENT DIAGNOSIS OF BREAST CANCER. IS GOING FOR FOLLOWING UP TESTING AND GRADING IN THE WEEKS TO COME. WILL UPDATE WITH MORE INFORMATION AS THE CARE TEAM MOVES FORWARD WITH TREATMENT PLANS. Biopsy on 08APR2021 indicated invasive ductal carcinoma' reason for change: Data Entry Error	Monica Feeley (b) (4)	30 Apr 2021 16:02:03

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[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 'no treatment or interventions as of now. These will likely occur later' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	30 Apr 2021 15:59:19
Query 'PV Query: Please confirm onset date as the subject had mammogram on 18 Mar 2021.' answered with '12APR2021 is correct. mammogram on 18MAR21 showed an abnormality but participant needed the biopsy to confirm. diagnosed on 12APR2021' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	30 Apr 2021 15:53:40
User opened query 'PV Query: Please confirm onset date as the subject had mammogram on 18 Mar 2021.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	27 Apr 2021 16:39:57
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) (b) (4)	27 Apr 2021 16:39:45
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) (b) (4)	27 Apr 2021 16:39:09
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	21 Apr 2021 19:28:26

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant reports recent diagnosis of Breast Cancer. Is going for following up testing and grading in the weeks to come. Will update with more information as the care team moves forward with treatment plans.'	Xhoi Mitre (b) (4)	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 21:28:51

US3432497

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 21:28:51

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:39:14

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:58:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:04:00
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:15:43

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
	(b) (4), (b) (6)	03 Dec 2020 17:46:36
DataPoint Verified.	Coder Import (b) (4)	14 Sep 2020 23:17:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 23:17:56
Data point term sent to Coder User entered 'Lexapro'	System Xhoi Mitre (b) (4)	14 Sep 2020 23:16:53
	(b) (4)	14 Sep 2020 23:16:23

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'Depression'	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '40'	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'mg (mg)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'once daily (QD)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'Oral (ORAL)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'UN UNK 2010'	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:16:23
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 23:16:23

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 23:16:23

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 23:16:23

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 23:19:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 23:19:12
	(b) (4)	
Data point term sent to Coder	System	14 Sep 2020 23:17:54
User entered 'vitamin b12'	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'General health'	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'I'	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'tablet (TABLET)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'once daily (QD)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'Oral (ORAL)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'UN UNK 2019'	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '0'	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'No (N)'	Xhoi Mitre (b) (4)	14 Sep 2020 23:17:01
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 23:17:01

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 23:17:01

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 23:17:01

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 13:56:28
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 13:56:28
	(b) (4)	
Data point term sent to Coder	System	05 Oct 2020 13:55:30
Coding entries removed.	(b) (4), (b) (6)	05 Oct 2020 13:54:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 18:24:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 18:24:51
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 18:24:09
Coding entries removed.	Phoebe Cunningham	30 Sep 2020 18:23:53
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 15:13:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 15:13:43
	(b) (4)	
Data point term sent to Coder	System	28 Sep 2020 14:18:09
User entered 'Magnesium'	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:08:21
User closed query 'Per source con-med log: Indication : General health: please review and edit.' (Site from CRA).	(b) (4), (b) (6)	07 Dec 2020 19:10:02
Query 'Per source con-med log: Indication : General health: please review and edit.' answered with 'Updated in medical history' (Site from CRA).	(b) (4), (b) (6)	07 Dec 2020 14:22:32
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User opened query 'Per source con-med log: Indication : General health: please review and edit.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:45:23
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'We will follow-up with participant on their next safety call to know the details about this indication, and update the source and EDC accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 15:18:38
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:59:28
User entered 'Leg cramps' reason for change: New Information	(b) (4), (b) (6)	05 Oct 2020 13:54:54
User entered 'General health'	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '250'	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 18:23:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 18:23:53
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	30 Sep 2020 18:23:53
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 14:17:12
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '25 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 14:17:12

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 14:27:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	22 Oct 2020 14:27:07
Data point term sent to Coder	System	22 Oct 2020 14:20:14
User entered 'ibuprofen'	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
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 FEVER 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 FEVER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 16:04:42
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER 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 FEVER did not meet the AE reporting criteria. ' answered with 'Fever solicited event, captured on Diary Dose 2, Day 2' (Site from DM).	Bruce Bausk (b) (4)	25 Jan 2021 22:19:39

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER 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 FEVER did not meet the AE reporting criteria. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 09:21:46
	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'fever'	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '400'	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'once (ONCE)'	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '15 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '15 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User entered empty.	System	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User entered empty.	System	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:18
User entered empty.	System	22 Oct 2020 14:19:46

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 16:21:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 16:21:32
Data point term sent to Coder	System	12 Nov 2020 16:20:16
User entered 'Influenza vaccine'	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'Influenza prophylaxis'	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of injection/vaccine 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)	26 Jan 2021 16:04:27
Query 'Per DM CLR: Please provide the actual dose for this medication instead of injection/vaccine count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with '1 shot, dose unknown' (Site from DM).	Bruce Bausk (b) (4)	25 Jan 2021 22:18:49
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of injection/vaccine 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)	25 Jan 2021 09:21:59
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'Other (OTHER)'	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'unit'	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'once (ONCE)'	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '5 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered '5 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:46:36
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User entered empty.	System	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User entered empty.	System	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:22
User entered empty.	System	12 Nov 2020 16:19:32

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
	(b) (4), (b) (6)	13 Apr 2021 13:55:12
DataPoint Verified.	Coder Import (b) (4)	06 Apr 2021 12:22:53
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:22:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	System	05 Apr 2021 16:56:17
Data point term sent to Coder User entered 'hydrocortisone (1%)'	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:12
	(b) (4)	
User entered 'No (N)'	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
	(b) (4), (b) (6)	13 Apr 2021 13:55:12
DataPoint Verified.	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
User entered 'non-pruritic excoriation (left wrist)'	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:12
User entered 'I'	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:12
User entered 'Other (OTHER)'	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:12
User entered 'application'	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:12
User entered 'as needed (PRN)'	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:12
User entered empty.	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:12
User entered 'Topical (TOPICAL)'	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:12
User entered empty.	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:12
User entered 'UN UNK 2018'	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:12
User entered '0'	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:12
User entered 'Yes (Y)'	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:12
User entered empty.	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:12
User entered 'No (N)'	Bethany Evans (b) (4)	05 Apr 2021 16:55:26
	(b) (4)	

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:55:26

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:55:26

US3432497

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:55:26

US3432497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:39:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:58:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:53:54
DataPoint Un-verified.	Bethany Evans (b) (4)	05 Apr 2021 16:49:49
Signature has been broken.	Bethany Evans (b) (4)	05 Apr 2021 16:49:49
User entered 'Yes (Y)' reason for change: New Information	Bethany Evans (b) (4)	05 Apr 2021 16:49:49
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:40:56
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:04:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 16:17:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 15:53:54

US3432497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:39:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 13:53:42
User entered '18 Mar 2021'	Bethany Evans (b) (4) (b) (4)	05 Apr 2021 16:50:17

US3432497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:39:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 13:53:42
User entered 'Mammogram'	Bethany Evans (b) (4) (b) (4)	05 Apr 2021 16:50:17

US3432497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:39:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:53:42
User entered 'Diagnostic (DIAGNOSTIC)'	Bethany Evans (b) (4)	05 Apr 2021 16:50:17
	(b) (4)	

US3432497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:39:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 13:53:42
User entered empty.	Bethany Evans (b) (4) (b) (4)	05 Apr 2021 16:50:17

US3432497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:39:14

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	30 Apr 2021 18:52:05
User entered '08 Apr 2021'	Monica Feeley (b) (4)	30 Apr 2021 15:57:20
	(b) (4)	

US3432497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:39:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	30 Apr 2021 18:52:05
User entered 'biopsy'	Monica Feeley (b) (4)	30 Apr 2021 15:57:20
	(b) (4)	

US3432497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:39:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	30 Apr 2021 18:52:05
User entered 'Diagnostic (DIAGNOSTIC)'	Monica Feeley (b) (4)	30 Apr 2021 15:57:20
	(b) (4)	

US3432497

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:39:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	30 Apr 2021 18:52:05
User entered empty.	Monica Feeley (b) (4) (b) (4)	30 Apr 2021 15:57:20

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'USA-US078-2021-MRNA-1273-P301000021'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'Yes (Y)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'Yes (Y)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'Lindsey'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'Baden'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'MA'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
User entered 'US'	System	21 Apr 2021 17:03:40

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 18:12:49
User entered '1'	System	21 Apr 2021 17:03:40

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'USA-US078-2021-MRNA-1273-P301000021'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'Yes (Y)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'Yes (Y)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'Lindsey'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'Baden'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'MA'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
User entered 'US'	System	21 Apr 2021 17:03:40

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 18:12:49
User entered '1'	System	21 Apr 2021 17:03:40

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:39:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
User entered '21/Apr/2021 13:03'	System	21 Apr 2021 17:03:40

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:39:14

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)	25 Apr 2021 11:23:40
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 17:03:40

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'USA-US078-2021-MRNA-1273-P301000021'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'Yes (Y)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'No (N)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'Yes (Y)'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'Lindsey'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'Baden'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:23:40
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:03:34
User entered 'MA'	System	21 Apr 2021 17:03:16

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:23:40
User entered 'US'	System	21 Apr 2021 17:03:40

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 18:12:49
User entered '1'	System	21 Apr 2021 17:03:40

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:39:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	30 Apr 2021 18:52:05
User entered '30/Apr/2021 14:12'	System	30 Apr 2021 18:12:49

US3432497

Folder: SAE USA-US078-2021-MRNA-1273-P301000021

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:39:14

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)	30 Apr 2021 18:52:05
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 18:12:49