

US3432617 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:40:46

All time stamps listed in this document are displayed in GMT

US3432617

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

[Participant ID](#)

US3432617

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

US3432617

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 20 OCT 2020

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

Folder OID SCRN

US3432617

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Date of Birth (MMM yyyy)	(b) (6) 1987
Age	33
Age Units	YEARS
Age (Derived)	33
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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

US3432617

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Date of Informed Consent (*dd MMM yyyy*) 20 OCT 2020

Month and Year of Informed Consent (derived) OCT 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3432617

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

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 03:33:14

Generated On: 09 Jun 2021 17:40:46

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

Condition	DRUG ADDICTION
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

Condition	DIABETES
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3432617

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

Condition	LEFT SHOULDER PAIN
Start date (dd MMM yyyy)	UN NOV 2019
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)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3432617

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	07:36 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 07:36
Height (<i>xxx.x</i>)	185 cm
Weight (<i>xxx.x</i>)	101.8 kg
BMI (<i>xxx.x</i>)	29.74434 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 03:33:14

Generated On: 09 Jun 2021 17:40:46

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

20 OCT 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: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

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 MAINTENANCE WORK

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 03:33:14

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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) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 20 OCT 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

What was the date of randomization? (dd MMM yyyy) 20 OCT 2020

What was the participant's randomization number? 147245

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 03:33:14

Generated On: 09 Jun 2021 17:40:46

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 03:33:14

Generated On: 09 Jun 2021 17:40:46

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 (<i>dd MMM yyyy</i>)	20 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	07:36 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 07:36
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (<i>xxx</i>)	101 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	077 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 03:33:14

Generated On: 09 Jun 2021 17:40:46

Height	ND - Not Done
Weight	ND - Not Done
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 (<i>dd MMM yyyy</i>)	20 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	9:32 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 9:32
Temperature (<i>xxx.x</i>)	37.1 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	091 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	070 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 03:33:14

Generated On: 09 Jun 2021 17:40:46

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 03:33:14

Generated On: 09 Jun 2021 17:40:46

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) 20 OCT 2020

What was the treatment time? (00:00-23:59) 08:58 (24 HR)

Treatment Date and Time (derived) 20 OCT 2020 08:58

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 03:33:14

Generated On: 09 Jun 2021 17:40:46

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 20 OCT 2020

Collection time (*00:00-23:59*) 08:07 (24 HR)

Collection date and time (derived) 20 OCT 2020 08:07

US3432617

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Collection date (<i>dd MMM yyyy</i>)	20 OCT 2020		
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:15	20 OCT 2020 08:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

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 17:40:46

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** 98.7 °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):

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

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

PC Time Stamp 20 OCT 2020 09:38

PC Open Date & Time 20 OCT 2020 09:18

PC Close Date & Time 20 OCT 2020 11:48

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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 21 OCT 2020 00:12
PC Open Date & Time 20 OCT 2020 12:43
PC Close Date & Time 21 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	21 OCT 2020 12:20
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

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
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
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 22 OCT 2020 12:00
PC Close Date & Time 23 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

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
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
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 23 OCT 2020 12:00
PC Close Date & Time 24 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 OCT 2020 07:13
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	26 OCT 2020 10:48
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 OCT 2020 07:26
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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

20 OCT 2020 09:39

PC Open Date & Time

20 OCT 2020 09:18

PC Close Date & Time

20 OCT 2020 11:48

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

21 OCT 2020 00:13

PC Open Date & Time

20 OCT 2020 12:43

PC Close Date & Time

21 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 2

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	21 OCT 2020 12:21
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 3

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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 4

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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 5

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

25 OCT 2020 07:13

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 6

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

26 OCT 2020 10:49

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 7

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

27 OCT 2020 07:26

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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

No

Yes

PC Time stamp	20 OCT 2020 09:40
PC Open Date & Time	20 OCT 2020 09:18
PC Close Date & Time	20 OCT 2020 11:48

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

No

Yes

PC Time stamp	21 OCT 2020 00:14
PC Open Date & Time	20 OCT 2020 12:43
PC Close Date & Time	21 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

	Yes <input type="checkbox"/>
PC Time stamp	21 OCT 2020 12:21
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

Yes

PC Time stamp

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

Yes

PC Time stamp

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

	Yes <input type="checkbox"/>
PC Time stamp	25 OCT 2020 07:14
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

	Yes <input type="checkbox"/>
PC Time stamp	26 OCT 2020 10:49
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

	Yes <input type="radio"/>
PC Time stamp	27 OCT 2020 07:27
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3432617

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 27 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3432617

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:32:57

Generated On: 09 Jun 2021 17:40:46

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432617

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (*dd MMM yyyy*)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3432617

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432617

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3432617

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432617

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 2 DEC 2020

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

Folder OID VISIT2

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

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 (<i>dd MMM yyyy</i>)	2 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	13:07 (24 HR)
Vital Signs Date and Time (derived)	2 DEC 2020 13:07
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	088 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	072 mmHg
Diastolic Blood Pressure units	MMHG

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

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 (<i>dd MMM yyyy</i>)	2 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	14:19 (24 HR)
Vital Signs Date and Time (derived)	2 DEC 2020 14:19
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	087 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	074 mmHg
Diastolic Blood Pressure units	MMHG

US3432617

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

2 DEC 2020

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

US3432617

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

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) 2 DEC 2020

What was the treatment time? (00:00-23:59) 13:45 (24 HR)

Treatment Date and Time (derived) 2 DEC 2020 13:45

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

US3432617

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 2 DEC 2020

Collection time (*00:00-23:59*) 13:28 (24 HR)

Collection date and time (derived) 2 DEC 2020 13:28

US3432617

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Collection date (<i>dd MMM yyyy</i>)			2 DEC 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:29	2 DEC 2020 13:29
Nasopharyngeal Swab 2	No		

US3432617

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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 98.8 °F

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

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

PC Time Stamp 02 DEC 2020 14:22

PC Open Date & Time 02 DEC 2020 14:05

PC Close Date & Time 02 DEC 2020 16:35

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 02 DEC 2020 17:30

PC Close Date & Time 03 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	03 DEC 2020 16:16
PC Open Date & Time	03 DEC 2020 12:00
PC Close Date & Time	04 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

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**
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
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 04 DEC 2020 12:00
PC Close Date & Time 05 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

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 _____
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 _____
To **PREVENT** pain or fever from occurring _____
PC Time Stamp _____
PC Open Date & Time 05 DEC 2020 12:00
PC Close Date & Time 06 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

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
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
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 06 DEC 2020 12:00
PC Close Date & Time 07 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 DEC 2020 09:01
PC Open Date & Time	07 DEC 2020 12:00
PC Close Date & Time	08 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 DEC 2020 11:56
PC Open Date & Time	08 DEC 2020 12:00
PC Close Date & Time	09 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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	02 DEC 2020 14:22
PC Open Date & Time	02 DEC 2020 14:05
PC Close Date & Time	02 DEC 2020 16:35

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

02 DEC 2020 17:30

PC Close Date & Time

03 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 2

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

03 DEC 2020 16:16

PC Open Date & Time

03 DEC 2020 12:00

PC Close Date & Time

04 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 3

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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

04 DEC 2020 12:00

PC Close Date & Time

05 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 4

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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

05 DEC 2020 12:00

PC Close Date & Time

06 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 5

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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

06 DEC 2020 12:00

PC Close Date & Time

07 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

08 DEC 2020 09:01

PC Open Date & Time

07 DEC 2020 12:00

PC Close Date & Time

08 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 7

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

09 DEC 2020 11:56

PC Open Date & Time

08 DEC 2020 12:00

PC Close Date & Time

09 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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

No

Yes

PC Time stamp	02 DEC 2020 14:23
PC Open Date & Time	02 DEC 2020 14:05
PC Close Date & Time	02 DEC 2020 16:35

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

No

Yes

PC Time stamp

PC Open Date & Time

02 DEC 2020 17:30

PC Close Date & Time

03 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

	Yes <input type="checkbox"/>
PC Time stamp	03 DEC 2020 16:17
PC Open Date & Time	03 DEC 2020 12:00
PC Close Date & Time	04 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

Yes

PC Time stamp

PC Open Date & Time

04 DEC 2020 12:00

PC Close Date & Time

05 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

Yes

PC Time stamp

PC Open Date & Time

05 DEC 2020 12:00

PC Close Date & Time

06 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

Yes

PC Time stamp

PC Open Date & Time

06 DEC 2020 12:00

PC Close Date & Time

07 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

	Yes <input type="checkbox"/>
PC Time stamp	08 DEC 2020 09:02
PC Open Date & Time	07 DEC 2020 12:00
PC Close Date & Time	08 DEC 2020 11:59

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

	Yes <input type="checkbox"/>
PC Time stamp	09 DEC 2020 11:56
PC Open Date & Time	08 DEC 2020 12:00
PC Close Date & Time	09 DEC 2020 11:59

US3432617

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:32:57

Generated On: 09 Jun 2021 17:40:46

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3432617

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432617

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:32:57

Generated On: 09 Jun 2021 17:40:46

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 16 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3432617

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:32:57

Generated On: 09 Jun 2021 17:40:46

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432617

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:32:57

Generated On: 09 Jun 2021 17:40:46

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3432617

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:32:57

Generated On: 09 Jun 2021 17:40:46

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432617

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 31 DEC 2020

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

Folder OID VISIT3

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	14:57 (24 HR)
Vital Signs Date and Time (derived)	31 DEC 2020 14:57
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (<i>xxx</i>)	104 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	54 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432617

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

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.

US3432617

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 31 DEC 2020

Collection time (*00:00-23:59*) 14:45 (24 HR)

Collection date and time (derived) 31 DEC 2020 14:45

US3432617

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 61

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	28 DEC 2020 16:47:21
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 <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 14:50:03
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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
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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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
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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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	11 FEB 2021 15:58:30
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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	18 FEB 2021 01:00:36
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 25 FEB 2021 22:08:30

Patient Cloud Open Date & Time 25 FEB 2021 00:01

Patient Cloud Close Date & Time 01 MAR 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 05 MAR 2021 11:59:30

Patient Cloud Open Date & Time 04 MAR 2021 00:01

Patient Cloud Close Date & Time 08 MAR 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 00:18:00
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 20 MAR 2021 08:01:06

Patient Cloud Open Date & Time 18 MAR 2021 00:01

Patient Cloud Close Date & Time 22 MAR 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 25 MAR 2021 00:37:41

Patient Cloud Open Date & Time 25 MAR 2021 00:01

Patient Cloud Close Date & Time 29 MAR 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 166

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

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 11:56:28
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 01:01:14
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 187

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

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 208

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 215

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

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 229

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

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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
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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 243

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

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 250

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

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#) 05 JUL 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 264

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 271

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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
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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	09 AUG 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#) 16 AUG 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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
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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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
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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 348

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 25 OCT 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	28 OCT 2021 00:01
Patient Cloud Close Date & Time	01 NOV 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

Patient Cloud Open Date & Time	25 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 411

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 13 DEC 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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
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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 27 DEC 2021 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 488

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	24 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

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07 MAR 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

Patient Cloud Open Date & Time	24 MAR 2022 00:01
Patient Cloud Close Date & Time	28 MAR 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

Patient Cloud Open Date & Time	02 JUN 2022 00:01
Patient Cloud Close Date & Time	06 JUN 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

Patient Cloud Open Date & Time	11 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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
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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 677

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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
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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#) 13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 17 OCT 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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
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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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
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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#) 10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#) 14 NOV 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	17 NOV 2022 00:01
Patient Cloud Close Date & Time	21 NOV 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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
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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

Patient Cloud Open Date & Time	24 NOV 2022 00:01
Patient Cloud Close Date & Time	28 NOV 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

Patient Cloud Open Date & Time	01 DEC 2022 00:01
Patient Cloud Close Date & Time	05 DEC 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission	
Patient Cloud Open Date & Time	08 DEC 2022 00:01
Patient Cloud Close Date & Time	12 DEC 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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°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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2022 23:59

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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
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

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 22 DEC 2022 00:01

[Patient Cloud Close Date & Time](#) 26 DEC 2022 23:59

US3432617

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:40:46

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		28 FEB 2021 02:53:45

US3432617

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:33:14

Generated On: 09 Jun 2021 17:40:46

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 29 JAN 2021

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

Comments PT WAS UNABLE TO BE REACHED FOR SAFETY CALL.
If Contact Not Made, please provide Comments PT WAS CALLED 1/25 AT 12:06,
1/25 AT 16:18, 1/27 AT 11:53 AND
1/29 AT 12:58.

US3432617

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432617

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

Was Contact Attempted? Yes
No

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

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

Comments MULTIPLE ATTEMPTS TO
CONTACT PARTICIPANT.
If Contact Not Made, please provide Comments STUDY TEAM LEFT
VOICEMAILS. NO CONTACT
MADE

US3432617

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3432617

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

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 _____

US3432617

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Date of Contact	18 NOV 2020
Time of Contact	16:00
Date and Time of Contact (derived)	18 NOV 2020 16:00
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/> Clinical Visit - Unscheduled <input type="radio"/> Safety Call <input type="radio"/> Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/> No <input type="radio"/>

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	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 12 NOV 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 type="radio"/>
Mild	<input checked="" type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	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 13 NOV 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 type="radio"/>
Mild	<input checked="" type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	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 14 NOV 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 type="radio"/>
Mild	<input checked="" type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	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 15 NOV 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 type="radio"/>
Mild	<input checked="" type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

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"/>

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	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 16 NOV 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 type="radio"/>
Mild	<input checked="" type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

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"/>

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	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 17 NOV 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 type="radio"/>
Mild	<input checked="" type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

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"/>

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	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 18 NOV 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 97.5 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2240

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

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"/>

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	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 19 NOV 2020

Assessment Not Done True

O2 Saturation _____

O2 Saturation Units _____

Temperature _____

Chills

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Cough

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Shortness of Breath

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Difficulty Breathing

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

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 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	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 20 NOV 2020

Assessment Not Done True

O2 Saturation

O2 Saturation Units

Temperature

Chills

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Cough

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Shortness of Breath

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Difficulty Breathing

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	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 21 NOV 2020

Assessment Not Done True

O2 Saturation _____

O2 Saturation Units _____

Temperature _____

Chills

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Cough

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Shortness of Breath

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Difficulty Breathing

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2240

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input 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 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 type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	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 22 NOV 2020

Assessment Not Done True

O2 Saturation _____

O2 Saturation Units _____

Temperature _____

Chills

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Cough

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Shortness of Breath

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Difficulty Breathing

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

364 of 2240

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" 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"/>

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	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 23 NOV 2020

Assessment Not Done True

O2 Saturation _____

O2 Saturation Units _____

Temperature _____

Chills

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Cough

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Shortness of Breath

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Difficulty Breathing

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

	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 24 NOV 2020

Assessment Not Done True

O2 Saturation _____

O2 Saturation Units _____

Temperature _____

Chills

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Cough

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Shortness of Breath

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Difficulty Breathing

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Date of Visit 18 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes
No

Date of Test 18 NOV 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes
No

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 0

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:40:46

Generate Next COVID-19 Assessment

Yes

No

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	20 NOV 2020
Day 5	Yes	23 NOV 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)	

US3432617

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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	SICKD1

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	16:18 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 16:18
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (<i>xxx</i>)	93 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432617

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

18 NOV 2020

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

US3432617

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 21:17:08

Generated On: 09 Jun 2021 17:40:46

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

18 NOV 2020

US3432617

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

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 31 DEC 2020

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

Folder OID UNBLND_DECIDE

US3432617

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

Form: Unblinding

Data signed: (b) (4) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

Date of updated informed consent (<i>dd MMM yyyy</i>)	31 DEC 2020
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	31 DEC 2020
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3432617

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 31 DEC 2020

Collection time (*00:00-23:59*) 14:45 (24 HR)

Collection date and time (derived) 31 DEC 2020 14:45

US3432617

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 31 DEC 2020

Collection time (*00:00 - 23:59*) 14:50

Collection Date and Time (derived) 31 DEC 2020 14:50

US3432617

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

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)

Data signed: (b) (4) 25 Apr 2021 11:29:48

Generated On: 09 Jun 2021 17:40:46

AEID

Adverse event

ERYTHEMATOUS PAPULE
(MID-STERNAL,
NON-URTICARIAL)

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes

No

Start date (dd MMM yyyy)

22 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Apr 2021 11:29:48

Generated On: 09 Jun 2021 17:40:46

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3432617

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Apr 2021 11:29:48

Generated On: 09 Jun 2021 17:40:46

AEID

Adverse event

GASTROENTERITIS

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes

No

Start date (dd MMM yyyy)

23 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

25 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Apr 2021 11:29:48

Generated On: 09 Jun 2021 17:40:46

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 25 Apr 2021 11:29:48

Generated On: 09 Jun 2021 17:40:46

AEID USA-US078-2021-MRNA-1273-P30
1000014

Adverse event OPIOID DETOX FOR DRUG
ADDICTION

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 10 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 3 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 10 JAN 2021

Hospital Discharge Date (dd MMM yyyy) 3 FEB 2021

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 25 Apr 2021 11:29:48

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT ADMITTED TO REHAB FACILITY FROM 10JAN21 UNTIL 03FEB21 FOR OPIOID DETOX
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 25 Apr 2021 11:29:48

Generated On: 09 Jun 2021 17:40:46

AEID

Adverse event

DIFFICULTY BREATHING

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes

No

Start date (dd MMM yyyy)

12 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

02 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 25 Apr 2021 11:29:48

Generated On: 09 Jun 2021 17:40:46

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

Serious Adverse Event Derived (CSA Programming Field Only) 0

Medically Attended AE Derived (CSA Programming Field Only) 1

Admitted to ICU Derived (CSA Programming Field Only) _____

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 03:32:56

Generated On: 09 Jun 2021 17:40:46

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 11:29:49

Generated On: 09 Jun 2021 17:40:46

Name of Medication BUPRENORPHINE/NALOXONE
(8/2MG)

Prophylaxis Yes
No

Indication DRUG ADDICTION

Dose per administration 8/2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

	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 FEB 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

Name of Medication MELFORMIN

Prophylaxis Yes
No

Indication DM2

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

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 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

Name of Medication NEURONTIN

Prophylaxis Yes
No

Indication LEFT SHOULDER PAIN

Dose per administration 300

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 11:29:49

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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*) 10 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

Name of Medication BUPROPION

Prophylaxis Yes
No

Indication DEPRESSION

Dose per administration 150

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)

402 of 2240

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

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) 10 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

Name of Medication ALBUTEROL SULFATE

Prophylaxis Yes
No

Indication DIFFICULTY BREATHING

Dose per administration 2

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)

404 of 2240

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 12 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

Name of Medication OMEGA VITAMINS

Prophylaxis Yes
No

Indication PROPHYLAXIS

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify TABLET

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)

406 of 2240

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

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 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication GASTROENTERITIS

Dose per administration UNK

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify UNK

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 2240

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Apr 2021 11:29:49

Generated On: 09 Jun 2021 17:40:46

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*) 24 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 24 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3432617

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3432617

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:40:46

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

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

SAEID	USA-US078-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

SAEID	USA-US078-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	05/FEB/2021 17:29
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.	<input checked="" type="checkbox"/> True

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 04 Apr 2021 21:17:08

Generated On: 09 Jun 2021 17:40:46

SAEID	USA-US078-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/MAR/2021 08:41
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.	<input checked="" type="checkbox"/> True

Audit

US3432617 (Prod: Brigham and Womens Hospital)

US3432617

Form: Participant Creation

Generated On: 09 Jun 2021 17:40:46

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:32:57
User entered 'US3432617'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Oct 2020 11:53:42

US3432617

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Megan Powell (b) (4)	20 Oct 2020 13:16:56

US3432617

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '20 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Oct 2020 11:53:44

US3432617

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Clinic (Clinic)'	Megan Powell (b) (4)	20 Oct 2020 13:16:56

US3432617

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'SCRN'	System	20 Oct 2020 13:16:56

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered (b) (6) 1987'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Oct 2020 11:53:45

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '33'	Megan Powell (b) (4)	20 Oct 2020 17:56:14

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'YEARS'	System	20 Oct 2020 17:56:14

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered '33'	System	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Male (M)'	Megan Powell (b) (4)	20 Oct 2020 17:56:14

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Megan Powell (b) (4)	20 Oct 2020 17:56:14

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 17:56:14

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '1'	Megan Powell (b) (4)	20 Oct 2020 17:56:14

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 17:56:14

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 17:56:14

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 17:56:14

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 17:56:14

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	Megan Powell (b) (4)	20 Oct 2020 17:56:14

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 17:56:14

US3432617

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:46

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 17:56:14

US3432617

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:46

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '20 Oct 2020'	Megan Powell (b) (4)	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'Oct 2020'	System	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered '2020'	System	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:46

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Amendment 4 (4)'	Megan Powell (b) (4)	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Megan Powell (b) (4)	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:46

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	Megan Powell (b) (4)	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	Megan Powell (b) (4)	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	20 Oct 2020 11:53:44

US3432617

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered '1'	System	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Megan Powell (b) (4)	20 Oct 2020 13:17:01

US3432617

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:40:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Megan Powell (b) (4)	20 Oct 2020 17:56:31

US3432617

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug dependence, LLT: Drug addiction - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 18:00:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 18:00:41
Data point term sent to Coder	System	20 Oct 2020 17:59:47
User entered 'Drug addiction'	Megan Powell (b) (4)	20 Oct 2020 17:59:31

US3432617

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'UN UNK 2004'	Megan Powell (b) (4)	20 Oct 2020 17:59:31

US3432617

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:46

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 17:59:31

US3432617

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 17:59:31

US3432617

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'UN Jun 2020'	Megan Powell (b) (4)	20 Oct 2020 17:59:31

US3432617

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 17:59:31

US3432617

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'Jan 2004'	System	20 Oct 2020 17:59:31

US3432617

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered '2004'	System	20 Oct 2020 17:59:31

US3432617

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'Jun 2020'	System	20 Oct 2020 17:59:31

US3432617

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered '2020'	System	20 Oct 2020 17:59:31

US3432617

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 18:03:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 18:03:39
Data point term sent to Coder	System	20 Oct 2020 18:02:52
User entered 'Diabetes'	Megan Powell (b) (4)	20 Oct 2020 18:02:37

US3432617

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'UN UNK 2015'	Megan Powell (b) (4)	20 Oct 2020 18:02:37

US3432617

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:46

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 18:02:37

US3432617

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Megan Powell (b) (4)	20 Oct 2020 18:02:37

US3432617

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	Megan Powell (b) (4)	20 Oct 2020 18:02:37

US3432617

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:46

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 18:02:37

US3432617

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'Jan 2015'	System	20 Oct 2020 18:02:37

US3432617

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered '2015'	System	20 Oct 2020 18:02:37

US3432617

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered empty.	System	20 Oct 2020 18:02:37

US3432617

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered empty.	System	20 Oct 2020 18:02:37

US3432617

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 15:24:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 15:24:35
Data point term sent to Coder	System	10 Nov 2020 15:23:38
User entered 'Left Shoulder Pain'	Kathleen Garvey (b) (4)	10 Nov 2020 15:23:32

US3432617

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'UN Nov 2019'	Kathleen Garvey (b) (4)	10 Nov 2020 15:23:32

US3432617

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:46

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Kathleen Garvey (b) (4)	10 Nov 2020 15:23:32

US3432617

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	10 Nov 2020 15:23:32

US3432617

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	Kathleen Garvey (b) (4)	10 Nov 2020 15:23:32

US3432617

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Kathleen Garvey (b) (4)	10 Nov 2020 15:23:32

US3432617

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'Nov 2019'	System	10 Nov 2020 15:23:32

US3432617

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered '2019'	System	10 Nov 2020 15:23:32

US3432617

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered empty.	System	10 Nov 2020 15:23:32

US3432617

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered empty.	System	10 Nov 2020 15:23:32

US3432617

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User coded data point as SOC: Psychiatric disorders, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 22:28:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 22:28:08
Data point term sent to Coder	System	07 Apr 2021 22:23:28
User entered 'depression'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:23:13

US3432617

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'un UNK 1995'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:23:13

US3432617

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:46

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:23:13

US3432617

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:23:13

US3432617

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	Natalie Izaguirre (b) (4)	07 Apr 2021 22:23:13

US3432617

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:46

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:23:13

US3432617

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'Jan 1995'	System	07 Apr 2021 22:23:13

US3432617

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered '1995'	System	07 Apr 2021 22:23:13

US3432617

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered empty.	System	07 Apr 2021 22:23:13

US3432617

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered empty.	System	07 Apr 2021 22:23:13

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Megan Powell (b) (4)	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '20 Oct 2020'	Megan Powell (b) (4)	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '07:36'	Megan Powell (b) (4)	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered '20 Oct 2020 07:36'	System	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '185' cm	Megan Powell (b) (4)	20 Oct 2020 18:05:19
DataPoint set to visible.	(b) (4) System	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '101.8' kg	Megan Powell (b) (4)	20 Oct 2020 18:05:19
DataPoint set to visible.	(b) (4) System	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered '29.74434'	System	20 Oct 2020 18:05:19
DataPoint set to visible.	System	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'kg/m2'	System	20 Oct 2020 18:05:19
DataPoint set to visible.	System	20 Oct 2020 13:17:14

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered missing code ND - Not Done.	Megan Powell (b) (4)	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	Megan Powell (b) (4)	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	Megan Powell (b) (4)	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered missing code ND - Not Done.	Megan Powell (b) (4)	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'bpm'	System	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered missing code ND - Not Done.	Megan Powell (b) (4)	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'breaths/min'	System	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered missing code ND - Not Done.	Megan Powell (b) (4)	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'mmHg'	System	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered missing code ND - Not Done.	Megan Powell (b) (4)	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'mmHg'	System	20 Oct 2020 18:05:19

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38

US3432617

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38

US3432617

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:46

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Megan Powell (b) (4)	20 Oct 2020 18:05:26

US3432617

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '20 Oct 2020'	Megan Powell (b) (4)	20 Oct 2020 18:05:26

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Maintenance Work'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '1'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '0'	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	Megan Powell (b) (4)	20 Oct 2020 18:06:35

US3432617

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,23NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:07:43
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,23NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'saliva log is entered into the system' (Site from DM).	Monica Feeley (b) (4)	08 Mar 2021 21:16:05
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,23NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 07:17:56
User entered 'Yes (Y)'	Megan Powell (b) (4)	20 Oct 2020 18:06:46

US3432617

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20OCT2020 is present in GCL but data not present in EDC, please clarify or reconcile' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 07:04:46
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20OCT2020 is present in GCL but data not present in EDC, please clarify or reconcile' answered with 'Updated' (Site from DM).	Alexander Mills (b) (4)	11 Dec 2020 17:31:16
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20OCT2020 is present in GCL but data not present in EDC, please clarify or reconcile' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 15:07:40
User entered '20 Oct 2020'	Megan Powell (b) (4)	20 Oct 2020 18:06:46

US3432617

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'Clinic (Clinic)'	Megan Powell (b) (4)	20 Oct 2020 18:06:46

US3432617

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'VISIT1'	System	20 Oct 2020 18:06:46

US3432617

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '20 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Oct 2020 12:03:42

US3432617

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:46

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '147245'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Oct 2020 12:03:42

US3432617

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Oct 2020 12:03:42

US3432617

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:46

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:07:40

US3432617

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:46

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:07:40

US3432617

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:07:40

US3432617

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:46

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Megan Powell (b) (4)	20 Oct 2020 18:07:40

US3432617

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:07:40

US3432617

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:46

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:07:40
DataPoint set to visible.	(b) (4) System	20 Oct 2020 13:17:14

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered missing code ND - Not Done.	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered missing code ND - Not Done.	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered missing code ND - Not Done.	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered missing code ND - Not Done.	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User accepted default value 'Pre-Dose (PREDOSE)'	Megan Powell (b) (4) (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '20 Oct 2020'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '07:36'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '20 Oct 2020 07:36'	System	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '36.4' C	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Other (Other)'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Infrared'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '101'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'bpm'	System	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '016'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'breaths/min'	System	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '131'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'mmHg'	System	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '077'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'mmHg'	System	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered missing code ND - Not Done.	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered missing code ND - Not Done.	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User accepted default value 'Post-Dose (POSTDOSE)'	Megan Powell (b) (4) (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '20 Oct 2020'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '9:32'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '20 Oct 2020 9:32'	System	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '37.1' C	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Oral (Oral)'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '091'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'bpm'	System	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '014'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'breaths/min'	System	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '123'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'mmHg'	System	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '070'	Megan Powell (b) (4)	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'mmHg'	System	20 Oct 2020 18:11:32

US3432617

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:46

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	Megan Powell (b) (4)	20 Oct 2020 18:11:37

US3432617

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	Megan Powell (b) (4)	20 Oct 2020 18:11:37

US3432617

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Megan Powell (b) (4)	20 Oct 2020 13:28:45

US3432617

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	Megan Powell (b) (4)	20 Oct 2020 13:28:45

US3432617

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	Megan Powell (b) (4)	20 Oct 2020 13:28:45

US3432617

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'MRNA-1273 OR PLACEBO'	System	20 Oct 2020 13:28:45

US3432617

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '20 Oct 2020'	Megan Powell (b) (4)	20 Oct 2020 13:28:45

US3432617

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '08:58'	Megan Powell (b) (4)	20 Oct 2020 13:28:45

US3432617

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '20 Oct 2020 08:58'	System	20 Oct 2020 13:28:45

US3432617

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Left Arm (LEFT ARM)'	Megan Powell (b) (4)	20 Oct 2020 13:28:45

US3432617

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'ONCE'	System	20 Oct 2020 13:28:45

US3432617

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'INTRAMUSCULAR'	System	20 Oct 2020 13:28:45

US3432617

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 20:40:55

US3432617

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '20 Oct 2020'	(b) (4), (b) (6)	02 Dec 2020 20:40:55

US3432617

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '08:07' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 20:42:25
User entered '09:32'	(b) (4), (b) (6)	02 Dec 2020 20:40:55

US3432617

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '20 Oct 2020 08:07'	System	02 Dec 2020 20:42:25
User entered '20 Oct 2020 09:32'	System	02 Dec 2020 20:40:55

US3432617

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '20 Oct 2020'	(b) (4), (b) (6)	02 Dec 2020 20:41:33

US3432617

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Dec 2020 20:41:33

US3432617

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 20:41:33

US3432617

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '08:15'	(b) (4), (b) (6)	02 Dec 2020 20:41:33

US3432617

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '20 Oct 2020 08:15'	System	02 Dec 2020 20:41:33

US3432617

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Dec 2020 20:41:33

US3432617

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	(b) (4), (b) (6)	02 Dec 2020 20:41:33

US3432617

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 20:41:33

US3432617

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered empty.	System	02 Dec 2020 20:41:33

US3432617

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 13:44:09

US3432617

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '1'	System	26 Oct 2020 13:44:09

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:37:11', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'da968b1f-175f-4045-9a82-cd3d17c1b8f8'	System	20 Oct 2020 13:38:24
User entered 'Yes (Y)'	System	20 Oct 2020 13:38:24

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:37:20', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'da968b1f-175f-4045-9a82-cd3d17c1b8f8' User entered '98.7'	System	20 Oct 2020 13:38:24
	System	20 Oct 2020 13:38:24

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:37:43', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'da968b1f-175f-4045-9a82-cd3d17c1b8f8'	System	20 Oct 2020 13:38:24
User entered 'Yes (Y)'	System	20 Oct 2020 13:38:24

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:38:10', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'da968b1f-175f-4045-9a82-cd3d17c1b8f8'	System	20 Oct 2020 13:38:24
User entered '0'	System	20 Oct 2020 13:38:24

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'in error. none taken in clinic' (Site from System).	(b) (4), (b) (6)	12 Feb 2021 11:10:28
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Monica Feeley (b) (4)	10 Feb 2021 22:01:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:38:10', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'da968b1f-175f-4045-9a82-cd3d17c1b8f8'	(b) (4)	
User entered '1'	System	20 Oct 2020 13:38:24
	System	20 Oct 2020 13:38:24
	System	20 Oct 2020 13:38:24

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:38:20', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'da968b1f-175f-4045-9a82-cd3d17c1b8f8' User entered '20 Oct 2020 09:38'	System	20 Oct 2020 13:38:24
	System	20 Oct 2020 13:38:24

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '20 Oct 2020 09:18'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '20 Oct 2020 11:48'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:12:32', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '6a848af0-3016-44b7-bae1-dc9babd16c95'	System	21 Oct 2020 04:12:55
User entered 'Yes (Y)'	System	21 Oct 2020 04:12:55

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:12:50', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '6a848af0-3016-44b7-bae1-dc9babd16c95'	System	21 Oct 2020 04:12:55
User entered '96.9'	System	21 Oct 2020 04:12:55

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:12:38', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '6a848af0-3016-44b7-bae1-dc9babd16c95'	System	21 Oct 2020 04:12:55
User entered 'No (N)'	System	21 Oct 2020 04:12:55

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:12:53', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '6a848af0-3016-44b7-bae1-dc9babd16c95'	System	21 Oct 2020 04:12:55
User entered '21 Oct 2020 00:12'	System	21 Oct 2020 04:12:55

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '20 Oct 2020 12:43'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 2'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:20:00', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'ba207e74-7557-407f-917c-048582ac9ad1' User entered 'Yes (Y)'	System	21 Oct 2020 16:20:18
	System	21 Oct 2020 16:20:18

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:20:05', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'ba207e74-7557-407f-917c-048582ac9ad1' User entered '97.9'	System	21 Oct 2020 16:20:18
	System	21 Oct 2020 16:20:18

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:20:09', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'ba207e74-7557-407f-917c-048582ac9ad1'	System	21 Oct 2020 16:20:18
User entered 'No (N)'	System	21 Oct 2020 16:20:18

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:20:14', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'ba207e74-7557-407f-917c-048582ac9ad1' User entered '21 Oct 2020 12:20'	System	21 Oct 2020 16:20:18
	System	21 Oct 2020 16:20:18

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 3'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 4'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 5'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:13:11', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '4af1ae14-a740-4ac0-bc64-e2309c5a7a2f' User entered 'Yes (Y)'	System	25 Oct 2020 11:13:26
	System	25 Oct 2020 11:13:26

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:13:16', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '4af1ae14-a740-4ac0-bc64-e2309c5a7a2f' User entered '96.7'	System	25 Oct 2020 11:13:26
	System	25 Oct 2020 11:13:26

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:13:19', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '4af1ae14-a740-4ac0-bc64-e2309c5a7a2f' User entered 'No (N)'	System	25 Oct 2020 11:13:26
	System	25 Oct 2020 11:13:26

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:13:22', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '4af1ae14-a740-4ac0-bc64-e2309c5a7a2f' User entered '25 Oct 2020 07:13'	System	25 Oct 2020 11:13:26
	System	25 Oct 2020 11:13:26

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 6'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:48:17', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'ca6ce3f6-28c8-4e3c-8f30-87fec444466b' User entered 'Yes (Y)'	System	26 Oct 2020 14:48:37
	System	26 Oct 2020 14:48:37

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:48:25', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'ca6ce3f6-28c8-4e3c-8f30-87fec444466b' User entered '96.8'	System	26 Oct 2020 14:48:37
	System	26 Oct 2020 14:48:37

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:48:27', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'ca6ce3f6-28c8-4e3c-8f30-87fec444466b'	System	26 Oct 2020 14:48:37
User entered 'No (N)'	System	26 Oct 2020 14:48:37

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:48:32', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'ca6ce3f6-28c8-4e3c-8f30-87fec444466b' User entered '26 Oct 2020 10:48'	System	26 Oct 2020 14:48:37
	System	26 Oct 2020 14:48:37

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 7'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:26:08', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'd2c9b748-32f7-4723-876a-89d7762f4451' User entered 'Yes (Y)'	System	27 Oct 2020 11:26:22
	System	27 Oct 2020 11:26:22

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:26:12', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'd2c9b748-32f7-4723-876a-89d7762f4451' User entered '97.2'	System	27 Oct 2020 11:26:22
	System	27 Oct 2020 11:26:22

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:26:15', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'd2c9b748-32f7-4723-876a-89d7762f4451'	System	27 Oct 2020 11:26:22
User entered 'No (N)'	System	27 Oct 2020 11:26:22

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:26:20', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'd2c9b748-32f7-4723-876a-89d7762f4451' User entered '27 Oct 2020 07:26'	System	27 Oct 2020 11:26:22
	System	27 Oct 2020 11:26:22

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:38:49', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '06300ec8-5bfc-41f7-a8a4-45a2955b8b57'	System	20 Oct 2020 13:39:23
User entered 'None (1)'	System	20 Oct 2020 13:39:23

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:38:56', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '06300ec8-5bfc-41f7-a8a4-45a2955b8b57'	System	20 Oct 2020 13:39:23
User entered 'No (N)'	System	20 Oct 2020 13:39:23

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:39:00', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '06300ec8-5bfc-41f7-a8a4-45a2955b8b57'	System	20 Oct 2020 13:39:23
User entered 'No (N)'	System	20 Oct 2020 13:39:23

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:39:15', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '06300ec8-5bfc-41f7-a8a4-45a2955b8b57'	System	20 Oct 2020 13:39:23
User entered 'None (1)'	System	20 Oct 2020 13:39:23

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:39:19', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '06300ec8-5bfc-41f7-a8a4-45a2955b8b57' User entered '20 Oct 2020 09:39'	System	20 Oct 2020 13:39:23
	System	20 Oct 2020 13:39:23

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '20 Oct 2020 09:18'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '20 Oct 2020 11:48'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:13:01', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'b628a5cf-ef7e-4ee7-b15e-e8f374afa83f' User entered 'None (1)'	System	21 Oct 2020 04:13:21
	System	21 Oct 2020 04:13:21

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:13:04', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'b628a5cf-ef7e-4ee7-b15e-e8f374afa83f' User entered 'No (N)'	System	21 Oct 2020 04:13:21
	System	21 Oct 2020 04:13:21

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:13:11', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'b628a5cf-ef7e-4ee7-b15e-e8f374afa83f' User entered 'No (N)'	System	21 Oct 2020 04:13:21
	System	21 Oct 2020 04:13:21

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:13:15', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'b628a5cf-ef7e-4ee7-b15e-e8f374afa83f' User entered 'None (1)'	System	21 Oct 2020 04:13:21
	System	21 Oct 2020 04:13:21

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:13:19', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'b628a5cf-ef7e-4ee7-b15e-e8f374afa83f' User entered '21 Oct 2020 00:13'	System	21 Oct 2020 04:13:21
	System	21 Oct 2020 04:13:21

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '20 Oct 2020 12:43'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 2'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:20:25', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f06ee853-082b-40fa-869a-6d317cf96b45'	System	21 Oct 2020 16:21:09
User entered 'None (1)'	System	21 Oct 2020 16:21:09

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:20:42', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f06ee853-082b-40fa-869a-6d317cf96b45'	System	21 Oct 2020 16:21:09
User entered 'No (N)'	System	21 Oct 2020 16:21:09

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:20:46', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f06ee853-082b-40fa-869a-6d317cf96b45'	System	21 Oct 2020 16:21:09
User entered 'No (N)'	System	21 Oct 2020 16:21:09

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:20:59', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f06ee853-082b-40fa-869a-6d317cf96b45'	System	21 Oct 2020 16:21:09
User entered 'None (1)'	System	21 Oct 2020 16:21:09

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:21:02', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f06ee853-082b-40fa-869a-6d317cf96b45' User entered '21 Oct 2020 12:21'	System	21 Oct 2020 16:21:09
	System	21 Oct 2020 16:21:09

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 3'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 4'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 5'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:11:59', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f781b69c-3c34-447d-8b01-c181bb73a6a5'	System	25 Oct 2020 11:13:09
User entered 'None (1)'	System	25 Oct 2020 11:13:09

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:12:47', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f781b69c-3c34-447d-8b01-c181bb73a6a5'	System	25 Oct 2020 11:13:09
User entered 'No (N)'	System	25 Oct 2020 11:13:09

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:12:52', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f781b69c-3c34-447d-8b01-c181bb73a6a5'	System	25 Oct 2020 11:13:09
User entered 'No (N)'	System	25 Oct 2020 11:13:09

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:13:00', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f781b69c-3c34-447d-8b01-c181bb73a6a5'	System	25 Oct 2020 11:13:09
User entered 'None (1)'	System	25 Oct 2020 11:13:09

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:13:04', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f781b69c-3c34-447d-8b01-c181bb73a6a5' User entered '25 Oct 2020 07:13'	System	25 Oct 2020 11:13:09
	System	25 Oct 2020 11:13:09

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 6'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:48:43', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '600e839d-c245-4b52-ba00-bb010ed3c9c3'	System	26 Oct 2020 14:49:10
User entered 'None (1)'	System	26 Oct 2020 14:49:10

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:48:47', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '600e839d-c245-4b52-ba00-bb010ed3c9c3'	System	26 Oct 2020 14:49:10
User entered 'No (N)'	System	26 Oct 2020 14:49:10

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:48:50', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '600e839d-c245-4b52-ba00-bb010ed3c9c3'	System	26 Oct 2020 14:49:10
User entered 'No (N)'	System	26 Oct 2020 14:49:10

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:49:02', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '600e839d-c245-4b52-ba00-bb010ed3c9c3'	System	26 Oct 2020 14:49:10
User entered 'None (1)'	System	26 Oct 2020 14:49:10

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:49:05', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '600e839d-c245-4b52-ba00-bb010ed3c9c3' User entered '26 Oct 2020 10:49'	System	26 Oct 2020 14:49:10
	System	26 Oct 2020 14:49:10

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 7'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:26:29', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '332b71e2-21c0-4301-b30f-5f469c1ad762'	System	27 Oct 2020 11:26:55
User entered 'None (1)'	System	27 Oct 2020 11:26:55

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:26:33', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '332b71e2-21c0-4301-b30f-5f469c1ad762'	System	27 Oct 2020 11:26:55
User entered 'No (N)'	System	27 Oct 2020 11:26:55

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:26:36', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '332b71e2-21c0-4301-b30f-5f469c1ad762'	System	27 Oct 2020 11:26:55
User entered 'No (N)'	System	27 Oct 2020 11:26:55

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:26:44', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '332b71e2-21c0-4301-b30f-5f469c1ad762'	System	27 Oct 2020 11:26:55
User entered 'None (1)'	System	27 Oct 2020 11:26:55

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:26:46', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '332b71e2-21c0-4301-b30f-5f469c1ad762' User entered '27 Oct 2020 07:26'	System	27 Oct 2020 11:26:55
	System	27 Oct 2020 11:26:55

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:39:31', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c747405b-4238-4dea-b5cb-f27a0ce648ef' User entered 'None (0)'	System	20 Oct 2020 13:40:37
	System	20 Oct 2020 13:40:37

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:39:37', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c747405b-4238-4dea-b5cb-f27a0ce648ef' User entered 'None (0)'	System	20 Oct 2020 13:40:37
	System	20 Oct 2020 13:40:37

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:39:41', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c747405b-4238-4dea-b5cb-f27a0ce648ef' User entered 'None (0)'	System	20 Oct 2020 13:40:37
	System	20 Oct 2020 13:40:37

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:39:44', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c747405b-4238-4dea-b5cb-f27a0ce648ef' User entered 'None (0)'	System	20 Oct 2020 13:40:37
	System	20 Oct 2020 13:40:37

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:39:53', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c747405b-4238-4dea-b5cb-f27a0ce648ef' User entered 'None (0)'	System	20 Oct 2020 13:40:37
	System	20 Oct 2020 13:40:37

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:40:03', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c747405b-4238-4dea-b5cb-f27a0ce648ef' User entered 'None (0)'	System	20 Oct 2020 13:40:37
	System	20 Oct 2020 13:40:37

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:40:27', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c747405b-4238-4dea-b5cb-f27a0ce648ef' User entered 'No (N)'	System	20 Oct 2020 13:40:37
	System	20 Oct 2020 13:40:37

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-20T09:40:32', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c747405b-4238-4dea-b5cb-f27a0ce648ef' User entered '20 Oct 2020 09:40'	System	20 Oct 2020 13:40:37
	System	20 Oct 2020 13:40:37

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '20 Oct 2020 09:18'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '20 Oct 2020 11:48'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:13:26', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'a4871453-f881-4580-a2f2-eddd87b276c7' User entered 'None (0)'	System	21 Oct 2020 04:14:09
	System	21 Oct 2020 04:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:13:29', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'a4871453-f881-4580-a2f2-eddd87b276c7' User entered 'None (0)'	System	21 Oct 2020 04:14:09
	System	21 Oct 2020 04:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:13:33', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'a4871453-f881-4580-a2f2-eddd87b276c7' User entered 'None (0)'	System	21 Oct 2020 04:14:09
	System	21 Oct 2020 04:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:13:36', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'a4871453-f881-4580-a2f2-eddd87b276c7' User entered 'None (0)'	System	21 Oct 2020 04:14:09
	System	21 Oct 2020 04:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:13:53', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'a4871453-f881-4580-a2f2-eddd87b276c7'	System	21 Oct 2020 04:14:09
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	21 Oct 2020 04:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:13:56', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'a4871453-f881-4580-a2f2-eddd87b276c7'	System	21 Oct 2020 04:14:09
User entered 'None (0)'	System	21 Oct 2020 04:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:14:03', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'a4871453-f881-4580-a2f2-eddd87b276c7'	System	21 Oct 2020 04:14:09
User entered 'No (N)'	System	21 Oct 2020 04:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T00:14:07', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'a4871453-f881-4580-a2f2-eddd87b276c7' User entered '21 Oct 2020 00:14'	System	21 Oct 2020 04:14:09
	System	21 Oct 2020 04:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '20 Oct 2020 12:43'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 2'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:21:07', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '832158e2-c4c0-4e76-98aa-c1d360322218' User entered 'None (0)'	System	21 Oct 2020 16:21:42
	System	21 Oct 2020 16:21:42

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:21:10', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '832158e2-c4c0-4e76-98aa-c1d360322218' User entered 'None (0)'	System	21 Oct 2020 16:21:42
	System	21 Oct 2020 16:21:42

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:21:14', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '832158e2-c4c0-4e76-98aa-c1d360322218' User entered 'None (0)'	System	21 Oct 2020 16:21:42
	System	21 Oct 2020 16:21:42

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:21:17', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '832158e2-c4c0-4e76-98aa-c1d360322218' User entered 'None (0)'	System	21 Oct 2020 16:21:42
	System	21 Oct 2020 16:21:42

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:21:24', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '832158e2-c4c0-4e76-98aa-c1d360322218'	System	21 Oct 2020 16:21:42
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	21 Oct 2020 16:21:42

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:21:27', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '832158e2-c4c0-4e76-98aa-c1d360322218' User entered 'None (0)'	System	21 Oct 2020 16:21:42
	System	21 Oct 2020 16:21:42

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:21:32', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '832158e2-c4c0-4e76-98aa-c1d360322218' User entered 'No (N)'	System	21 Oct 2020 16:21:42
	System	21 Oct 2020 16:21:42

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-21T12:21:35', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '832158e2-c4c0-4e76-98aa-c1d360322218' User entered '21 Oct 2020 12:21'	System	21 Oct 2020 16:21:42
	System	21 Oct 2020 16:21:42

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 3'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 4'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 5'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:13:27', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '7c1270a2-624d-4af3-a03e-e71c72a34730' User entered 'None (0)'	System	25 Oct 2020 11:14:09
	System	25 Oct 2020 11:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:13:32', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '7c1270a2-624d-4af3-a03e-e71c72a34730' User entered 'None (0)'	System	25 Oct 2020 11:14:09
	System	25 Oct 2020 11:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:13:41', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '7c1270a2-624d-4af3-a03e-e71c72a34730'	System	25 Oct 2020 11:14:09
User entered 'No interference with activity (1)'	System	25 Oct 2020 11:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:13:44', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '7c1270a2-624d-4af3-a03e-e71c72a34730'	System	25 Oct 2020 11:14:09
User entered 'No interference with activity (1)'	System	25 Oct 2020 11:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:13:51', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '7c1270a2-624d-4af3-a03e-e71c72a34730'	System	25 Oct 2020 11:14:09
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	25 Oct 2020 11:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:13:59', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '7c1270a2-624d-4af3-a03e-e71c72a34730'	System	25 Oct 2020 11:14:09
User entered 'None (0)'	System	25 Oct 2020 11:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:14:04', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '7c1270a2-624d-4af3-a03e-e71c72a34730'	System	25 Oct 2020 11:14:09
User entered 'No (N)'	System	25 Oct 2020 11:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-25T07:14:06', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '7c1270a2-624d-4af3-a03e-e71c72a34730' User entered '25 Oct 2020 07:14'	System	25 Oct 2020 11:14:09
	System	25 Oct 2020 11:14:09

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 6'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:49:09', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e08dce62-b075-4380-820a-d73d33fb51a9'	System	26 Oct 2020 14:49:28
User entered 'None (0)'	System	26 Oct 2020 14:49:28

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:49:11', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e08dce62-b075-4380-820a-d73d33fb51a9' User entered 'None (0)'	System	26 Oct 2020 14:49:28
	System	26 Oct 2020 14:49:28

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:49:14', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e08dce62-b075-4380-820a-d73d33fb51a9'	System	26 Oct 2020 14:49:28
User entered 'None (0)'	System	26 Oct 2020 14:49:28

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:49:17', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e08dce62-b075-4380-820a-d73d33fb51a9'	System	26 Oct 2020 14:49:28
User entered 'None (0)'	System	26 Oct 2020 14:49:28

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:49:19', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e08dce62-b075-4380-820a-d73d33fb51a9' User entered 'None (0)'	System	26 Oct 2020 14:49:28
	System	26 Oct 2020 14:49:28

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:49:21', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e08dce62-b075-4380-820a-d73d33fb51a9'	System	26 Oct 2020 14:49:28
User entered 'None (0)'	System	26 Oct 2020 14:49:28

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:49:22', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e08dce62-b075-4380-820a-d73d33fb51a9'	System	26 Oct 2020 14:49:28
User entered 'No (N)'	System	26 Oct 2020 14:49:28

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-26T10:49:25', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e08dce62-b075-4380-820a-d73d33fb51a9' User entered '26 Oct 2020 10:49'	System	26 Oct 2020 14:49:28
	System	26 Oct 2020 14:49:28

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	20 Oct 2020 13:28:45
User entered 'Day 7'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:26:52', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '17feda89-7b5a-4ff9-b870-90e1d1f8c673'	System	27 Oct 2020 11:27:17
User entered 'None (0)'	System	27 Oct 2020 11:27:17

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:26:56', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '17feda89-7b5a-4ff9-b870-90e1d1f8c673'	System	27 Oct 2020 11:27:17
User entered 'None (0)'	System	27 Oct 2020 11:27:17

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:27:00', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '17feda89-7b5a-4ff9-b870-90e1d1f8c673'	System	27 Oct 2020 11:27:17
User entered 'None (0)'	System	27 Oct 2020 11:27:17

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:27:03', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '17feda89-7b5a-4ff9-b870-90e1d1f8c673'	System	27 Oct 2020 11:27:17
User entered 'None (0)'	System	27 Oct 2020 11:27:17

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:27:06', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '17feda89-7b5a-4ff9-b870-90e1d1f8c673'	System	27 Oct 2020 11:27:17
User entered 'None (0)'	System	27 Oct 2020 11:27:17

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:27:08', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '17feda89-7b5a-4ff9-b870-90e1d1f8c673'	System	27 Oct 2020 11:27:17
User entered 'None (0)'	System	27 Oct 2020 11:27:17

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:27:11', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '17feda89-7b5a-4ff9-b870-90e1d1f8c673'	System	27 Oct 2020 11:27:17
User entered 'Yes (Y)'	System	27 Oct 2020 11:27:17

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFD01FD6-D905-42DE-9517-91E0E4A837A6)', Time: '2020-10-27T07:27:13', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '17feda89-7b5a-4ff9-b870-90e1d1f8c673' User entered '27 Oct 2020 07:27'	System	27 Oct 2020 11:27:17
	System	27 Oct 2020 11:27:17

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 13:28:45

US3432617

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 13:28:45

US3432617

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 13:03:10

US3432617

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 13:03:10

US3432617

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Oct 2020 13:03:10

US3432617

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 13:03:10

US3432617

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 13:03:14

US3432617

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '1'	System	27 Oct 2020 13:03:14

US3432617

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 15:53:31

US3432617

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '3 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 15:53:31

US3432617

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Nov 2020 15:53:31

US3432617

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 15:53:31

US3432617

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 15:53:43

US3432617

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'I'	System	03 Nov 2020 15:53:43

US3432617

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	10 Nov 2020 15:19:58

US3432617

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '10 Nov 2020'	Kathleen Garvey (b) (4)	10 Nov 2020 15:19:58

US3432617

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	10 Nov 2020 15:19:58

US3432617

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Kathleen Garvey (b) (4)	10 Nov 2020 15:19:58

US3432617

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	10 Nov 2020 15:20:03

US3432617

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '1'	System	10 Nov 2020 15:20:03

US3432617

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 19:40:39

US3432617

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 11:59:32
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Due to illness visit, visit 2 was delayed. Visit 2 occurred out of window.' (Site from System).	Alexander Mills (b) (4)	08 Dec 2020 17:40:01
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Dec 2020 19:40:39
User entered '2 Dec 2020'	(b) (4), (b) (6)	02 Dec 2020 19:40:39

US3432617

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Dec 2020 19:40:39

US3432617

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'VISIT2'	System	02 Dec 2020 19:40:39

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '2 Dec 2020'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '13:07'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '2 Dec 2020 13:07'	System	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '98.4' F	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '088'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'bpm'	System	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '16'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'breaths/min'	System	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '119'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'mmHg'	System	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '072'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'mmHg'	System	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '2 Dec 2020'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '14:19'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '2 Dec 2020 14:19'	System	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '98.8' F	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '087'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'bpm'	System	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '15'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'breaths/min'	System	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '126'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'mmHg'	System	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '074'	(b) (4), (b) (6)	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'mmHg'	System	02 Dec 2020 19:42:42

US3432617

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 19:43:06

US3432617

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '2 Dec 2020'	(b) (4), (b) (6)	02 Dec 2020 19:43:06

US3432617

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 18:55:15

US3432617

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 18:55:15

US3432617

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 18:55:15

US3432617

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'MRNA-1273 OR PLACEBO'	System	02 Dec 2020 18:55:15

US3432617

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '2 Dec 2020'	(b) (4), (b) (6)	02 Dec 2020 18:55:15

US3432617

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '13:45'	(b) (4), (b) (6)	02 Dec 2020 18:55:15

US3432617

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '2 Dec 2020 13:45'	System	02 Dec 2020 18:55:15

US3432617

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	02 Dec 2020 18:55:15

US3432617

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'ONCE'	System	02 Dec 2020 18:55:15

US3432617

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'INTRAMUSCULAR'	System	02 Dec 2020 18:55:15

US3432617

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 19:46:59

US3432617

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '2 Dec 2020'	(b) (4), (b) (6)	02 Dec 2020 19:46:59

US3432617

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '13:28'	(b) (4), (b) (6)	02 Dec 2020 19:46:59

US3432617

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '2 Dec 2020 13:28'	System	02 Dec 2020 19:46:59

US3432617

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '2 Dec 2020'	(b) (4), (b) (6)	02 Dec 2020 19:47:51

US3432617

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Dec 2020 19:47:51

US3432617

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 19:47:51

US3432617

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '13:29'	(b) (4), (b) (6)	02 Dec 2020 19:47:51

US3432617

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '2 Dec 2020 13:29'	System	02 Dec 2020 19:47:51

US3432617

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Dec 2020 19:47:51

US3432617

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	(b) (4), (b) (6)	02 Dec 2020 19:47:51

US3432617

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 19:47:51

US3432617

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered empty.	System	02 Dec 2020 19:47:51

US3432617

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 19:55:12

US3432617

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '1'	System	02 Dec 2020 19:55:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:21:56', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e527d005-9bd6-4302-8180-fc64aa46032b'	System	02 Dec 2020 19:22:19
User entered 'Yes (Y)'	System	02 Dec 2020 19:22:19

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:22:04', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e527d005-9bd6-4302-8180-fc64aa46032b'	System	02 Dec 2020 19:22:19
User entered '98.8'	System	02 Dec 2020 19:22:19

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:22:08', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e527d005-9bd6-4302-8180-fc64aa46032b'	System	02 Dec 2020 19:22:19
User entered 'No (N)'	System	02 Dec 2020 19:22:19

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:22:12', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e527d005-9bd6-4302-8180-fc64aa46032b' User entered '02 Dec 2020 14:22'	System	02 Dec 2020 19:22:19
	System	02 Dec 2020 19:22:19

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '02 Dec 2020 14:05'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '02 Dec 2020 16:35'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 1, after vaccination (at home)'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '02 Dec 2020 17:30'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '03 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 2'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:15:57', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f0ffffb-bd4a-4d68-aa8b-74be3456d11e'	System	03 Dec 2020 21:16:15
User entered 'Yes (Y)'	System	03 Dec 2020 21:16:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:16:02', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f0ffffb-bd4a-4d68-aa8b-74be3456d11e'	System	03 Dec 2020 21:16:15
User entered '97.6'	System	03 Dec 2020 21:16:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:16:06', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f0ffffb-bd4a-4d68-aa8b-74be3456d11e'	System	03 Dec 2020 21:16:15
User entered 'No (N)'	System	03 Dec 2020 21:16:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:16:10', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f0ffffb-bd4a-4d68-aa8b-74be3456d11e' User entered '03 Dec 2020 16:16'	System	03 Dec 2020 21:16:15
	System	03 Dec 2020 21:16:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '03 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '04 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 3'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '04 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '05 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 4'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '05 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '06 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 5'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '06 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '07 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 6'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:00:57', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '91735962-6b6b-441b-805e-8c444d64e667'	System	08 Dec 2020 14:01:25
User entered 'Yes (Y)'	System	08 Dec 2020 14:01:25

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:05', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '91735962-6b6b-441b-805e-8c444d64e667'	System	08 Dec 2020 14:01:25
User entered '97.7'	System	08 Dec 2020 14:01:25

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:09', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '91735962-6b6b-441b-805e-8c444d64e667'	System	08 Dec 2020 14:01:25
User entered 'No (N)'	System	08 Dec 2020 14:01:25

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:20', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '91735962-6b6b-441b-805e-8c444d64e667'	System	08 Dec 2020 14:01:25
User entered '08 Dec 2020 09:01'	System	08 Dec 2020 14:01:25

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '07 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '08 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 7'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:07', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'b63c93df-348d-42d4-a2ec-46ff575110ba'	System	09 Dec 2020 16:56:22
User entered 'Yes (Y)'	System	09 Dec 2020 16:56:22

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:11', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'b63c93df-348d-42d4-a2ec-46ff575110ba'	System	09 Dec 2020 16:56:22
User entered '97.4'	System	09 Dec 2020 16:56:22

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:14', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'b63c93df-348d-42d4-a2ec-46ff575110ba'	System	09 Dec 2020 16:56:22
User entered 'No (N)'	System	09 Dec 2020 16:56:22

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:17', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'b63c93df-348d-42d4-a2ec-46ff575110ba' User entered '09 Dec 2020 11:56'	System	09 Dec 2020 16:56:22
	System	09 Dec 2020 16:56:22

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '08 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '09 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:22:22', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '30006ade-8f8c-4ec3-88b3-0f393d0eae28'	System	02 Dec 2020 19:22:46
User entered 'None (1)'	System	02 Dec 2020 19:22:46

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:22:28', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '30006ade-8f8c-4ec3-88b3-0f393d0eae28'	System	02 Dec 2020 19:22:46
User entered 'No (N)'	System	02 Dec 2020 19:22:46

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:22:31', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '30006ade-8f8c-4ec3-88b3-0f393d0eae28'	System	02 Dec 2020 19:22:46
User entered 'No (N)'	System	02 Dec 2020 19:22:46

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:22:39', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '30006ade-8f8c-4ec3-88b3-0f393d0eae28'	System	02 Dec 2020 19:22:46
User entered 'None (1)'	System	02 Dec 2020 19:22:46

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:22:42', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '30006ade-8f8c-4ec3-88b3-0f393d0eae28'	System	02 Dec 2020 19:22:46
User entered '02 Dec 2020 14:22'	System	02 Dec 2020 19:22:46

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '02 Dec 2020 14:05'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '02 Dec 2020 16:35'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 1, after vaccination (at home)'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '02 Dec 2020 17:30'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '03 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 2'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:16:18', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '107d8d2d-ca3c-457c-b6d4-c5e577b1186a'	System	03 Dec 2020 21:16:58
User entered 'None (1)'	System	03 Dec 2020 21:16:58

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:16:34', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '107d8d2d-ca3c-457c-b6d4-c5e577b1186a'	System	03 Dec 2020 21:16:58
User entered 'No (N)'	System	03 Dec 2020 21:16:58

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:16:40', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '107d8d2d-ca3c-457c-b6d4-c5e577b1186a'	System	03 Dec 2020 21:16:58
User entered 'No (N)'	System	03 Dec 2020 21:16:58

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:16:48', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '107d8d2d-ca3c-457c-b6d4-c5e577b1186a'	System	03 Dec 2020 21:16:58
User entered 'None (1)'	System	03 Dec 2020 21:16:58

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:16:51', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '107d8d2d-ca3c-457c-b6d4-c5e577b1186a'	System	03 Dec 2020 21:16:58
User entered '03 Dec 2020 16:16'	System	03 Dec 2020 21:16:58

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '03 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '04 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 3'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '04 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '05 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 4'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '05 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '06 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 5'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '06 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '07 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 6'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:24', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f1cbbc0c-d69c-441d-8cef-c96cd891042c'	System	08 Dec 2020 14:01:41
User entered 'None (1)'	System	08 Dec 2020 14:01:41

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:29', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f1cbbc0c-d69c-441d-8cef-c96cd891042c'	System	08 Dec 2020 14:01:41
User entered 'No (N)'	System	08 Dec 2020 14:01:41

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:31', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f1cbbc0c-d69c-441d-8cef-c96cd891042c'	System	08 Dec 2020 14:01:41
User entered 'No (N)'	System	08 Dec 2020 14:01:41

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:34', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f1cbbc0c-d69c-441d-8cef-c96cd891042c'	System	08 Dec 2020 14:01:41
User entered 'None (1)'	System	08 Dec 2020 14:01:41

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:36', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f1cbbc0c-d69c-441d-8cef-c96cd891042c' User entered '08 Dec 2020 09:01'	System	08 Dec 2020 14:01:41
	System	08 Dec 2020 14:01:41

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '07 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '08 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 7'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:21', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '0b05a3d4-870d-4d33-af93-f6ee371c97d2'	System	09 Dec 2020 16:56:38
User entered 'None (1)'	System	09 Dec 2020 16:56:38

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:24', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '0b05a3d4-870d-4d33-af93-f6ee371c97d2'	System	09 Dec 2020 16:56:38
User entered 'No (N)'	System	09 Dec 2020 16:56:38

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:27', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '0b05a3d4-870d-4d33-af93-f6ee371c97d2'	System	09 Dec 2020 16:56:38
User entered 'No (N)'	System	09 Dec 2020 16:56:38

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:29', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '0b05a3d4-870d-4d33-af93-f6ee371c97d2'	System	09 Dec 2020 16:56:38
User entered 'None (1)'	System	09 Dec 2020 16:56:38

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:31', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '0b05a3d4-870d-4d33-af93-f6ee371c97d2'	System	09 Dec 2020 16:56:38
User entered '09 Dec 2020 11:56'	System	09 Dec 2020 16:56:38

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '08 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '09 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:22:48', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '6f3969db-faeb-4475-b476-0dab8346542d'	System	02 Dec 2020 19:23:20
User entered 'None (0)'	System	02 Dec 2020 19:23:20

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:22:50', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '6f3969db-faeb-4475-b476-0dab8346542d'	System	02 Dec 2020 19:23:20
User entered 'None (0)'	System	02 Dec 2020 19:23:20

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:22:55', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '6f3969db-faeb-4475-b476-0dab8346542d'	System	02 Dec 2020 19:23:20
User entered 'None (0)'	System	02 Dec 2020 19:23:20

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:23:02', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '6f3969db-faeb-4475-b476-0dab8346542d'	System	02 Dec 2020 19:23:20
User entered 'None (0)'	System	02 Dec 2020 19:23:20

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:23:05', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '6f3969db-faeb-4475-b476-0dab8346542d'	System	02 Dec 2020 19:23:20
User entered 'None (0)'	System	02 Dec 2020 19:23:20

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:23:07', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '6f3969db-faeb-4475-b476-0dab8346542d'	System	02 Dec 2020 19:23:20
User entered 'None (0)'	System	02 Dec 2020 19:23:20

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:23:12', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '6f3969db-faeb-4475-b476-0dab8346542d'	System	02 Dec 2020 19:23:20
User entered 'No (N)'	System	02 Dec 2020 19:23:20

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-02T14:23:15', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '6f3969db-faeb-4475-b476-0dab8346542d' User entered '02 Dec 2020 14:23'	System	02 Dec 2020 19:23:20
	System	02 Dec 2020 19:23:20

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '02 Dec 2020 14:05'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '02 Dec 2020 16:35'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 1, after vaccination (at home)'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '02 Dec 2020 17:30'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '03 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 2'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:16:56', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c25b2a04-3291-491e-b6c0-a95aa49ab7e3'	System	03 Dec 2020 21:17:19
User entered 'None (0)'	System	03 Dec 2020 21:17:19

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:16:59', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c25b2a04-3291-491e-b6c0-a95aa49ab7e3'	System	03 Dec 2020 21:17:19
User entered 'None (0)'	System	03 Dec 2020 21:17:19

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:17:02', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c25b2a04-3291-491e-b6c0-a95aa49ab7e3'	System	03 Dec 2020 21:17:19
User entered 'None (0)'	System	03 Dec 2020 21:17:19

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:17:06', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c25b2a04-3291-491e-b6c0-a95aa49ab7e3'	System	03 Dec 2020 21:17:19
User entered 'None (0)'	System	03 Dec 2020 21:17:19

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:17:08', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c25b2a04-3291-491e-b6c0-a95aa49ab7e3'	System	03 Dec 2020 21:17:19
User entered 'None (0)'	System	03 Dec 2020 21:17:19

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:17:11', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c25b2a04-3291-491e-b6c0-a95aa49ab7e3'	System	03 Dec 2020 21:17:19
User entered 'None (0)'	System	03 Dec 2020 21:17:19

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:17:13', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c25b2a04-3291-491e-b6c0-a95aa49ab7e3'	System	03 Dec 2020 21:17:19
User entered 'No (N)'	System	03 Dec 2020 21:17:19

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-03T16:17:15', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'c25b2a04-3291-491e-b6c0-a95aa49ab7e3'	System	03 Dec 2020 21:17:19
User entered '03 Dec 2020 16:17'	System	03 Dec 2020 21:17:19

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '03 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '04 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 3'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '04 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '05 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 4'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '05 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '06 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 5'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '06 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '07 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 6'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:41', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '2c369c4b-abbd-4988-974c-4a13b412bef6'	System	08 Dec 2020 14:02:09
User entered 'None (0)'	System	08 Dec 2020 14:02:09

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:44', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '2c369c4b-abbd-4988-974c-4a13b412bef6'	System	08 Dec 2020 14:02:09
User entered 'None (0)'	System	08 Dec 2020 14:02:09

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:46', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '2c369c4b-abbd-4988-974c-4a13b412bef6'	System	08 Dec 2020 14:02:09
User entered 'None (0)'	System	08 Dec 2020 14:02:09

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:48', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '2c369c4b-abbd-4988-974c-4a13b412bef6'	System	08 Dec 2020 14:02:09
User entered 'None (0)'	System	08 Dec 2020 14:02:09

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:50', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '2c369c4b-abbd-4988-974c-4a13b412bef6'	System	08 Dec 2020 14:02:09
User entered 'None (0)'	System	08 Dec 2020 14:02:09

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:52', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '2c369c4b-abbd-4988-974c-4a13b412bef6'	System	08 Dec 2020 14:02:09
User entered 'None (0)'	System	08 Dec 2020 14:02:09

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:01:56', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '2c369c4b-abbd-4988-974c-4a13b412bef6'	System	08 Dec 2020 14:02:09
User entered 'No (N)'	System	08 Dec 2020 14:02:09

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-08T09:02:01', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '2c369c4b-abbd-4988-974c-4a13b412bef6'	System	08 Dec 2020 14:02:09
User entered '08 Dec 2020 09:02'	System	08 Dec 2020 14:02:09

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '07 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '08 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
Data entry locked.	System	02 Dec 2020 18:55:15
User entered 'Day 7'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:35', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '1eac79c0-20df-477c-888a-2837bde9b187'	System	09 Dec 2020 16:56:54
User entered 'None (0)'	System	09 Dec 2020 16:56:54

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:37', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '1eac79c0-20df-477c-888a-2837bde9b187'	System	09 Dec 2020 16:56:54
User entered 'None (0)'	System	09 Dec 2020 16:56:54

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:38', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '1eac79c0-20df-477c-888a-2837bde9b187'	System	09 Dec 2020 16:56:54
User entered 'None (0)'	System	09 Dec 2020 16:56:54

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:40', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '1eac79c0-20df-477c-888a-2837bde9b187'	System	09 Dec 2020 16:56:54
User entered 'None (0)'	System	09 Dec 2020 16:56:54

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:42', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '1eac79c0-20df-477c-888a-2837bde9b187'	System	09 Dec 2020 16:56:54
User entered 'None (0)'	System	09 Dec 2020 16:56:54

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:44', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '1eac79c0-20df-477c-888a-2837bde9b187'	System	09 Dec 2020 16:56:54
User entered 'None (0)'	System	09 Dec 2020 16:56:54

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

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 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:47', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '1eac79c0-20df-477c-888a-2837bde9b187'	System	09 Dec 2020 16:56:54
User entered 'No (N)'	System	09 Dec 2020 16:56:54

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-09T11:56:49', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '1eac79c0-20df-477c-888a-2837bde9b187' User entered '09 Dec 2020 11:56'	System	09 Dec 2020 16:56:54
	System	09 Dec 2020 16:56:54

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '08 Dec 2020 12:00'	System	02 Dec 2020 18:55:15

US3432617

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:12
User entered '09 Dec 2020 11:59'	System	02 Dec 2020 18:55:15

US3432617

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	09 Dec 2020 21:07:42

US3432617

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '9 Dec 2020'	Kathleen Garvey (b) (4)	09 Dec 2020 21:07:42

US3432617

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	09 Dec 2020 21:07:42

US3432617

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Kathleen Garvey (b) (4)	09 Dec 2020 21:07:42

US3432617

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	09 Dec 2020 21:07:48

US3432617

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'I'	System	09 Dec 2020 21:07:48

US3432617

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 17:00:11

US3432617

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '16 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 17:00:11

US3432617

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Dec 2020 17:00:11

US3432617

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 17:00:11

US3432617

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 17:00:16

US3432617

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'I'	System	16 Dec 2020 17:00:16

US3432617

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Dec 2020 21:03:17

US3432617

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '23 Dec 2020'	(b) (4), (b) (6)	23 Dec 2020 21:03:17

US3432617

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Dec 2020 21:03:17

US3432617

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 21:03:17

US3432617

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Dec 2020 21:03:21

US3432617

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'I'	System	23 Dec 2020 21:03:21

US3432617

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Dec 2020 20:22:55

US3432617

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '31 Dec 2020'	(b) (4), (b) (6)	31 Dec 2020 20:22:55

US3432617

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	31 Dec 2020 20:22:55

US3432617

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'VISIT3'	System	31 Dec 2020 20:22:55

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '31 Dec 2020'	(b) (4), (b) (6)	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '14:57'	(b) (4), (b) (6)	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '31 Dec 2020 14:57'	System	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '97.1' F	(b) (4), (b) (6)	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Other (Other)'	(b) (4), (b) (6)	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'infrared'	(b) (4), (b) (6)	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '104'	(b) (4), (b) (6)	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'bpm'	System	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '12'	(b) (4), (b) (6)	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'breaths/min'	System	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '99'	(b) (4), (b) (6)	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'mmHg'	System	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	07 Jan 2021 13:48:49
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 20:26:54
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		31 Dec 2020 20:26:50
User entered '54'	(b) (4), (b) (6)	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'mmHg'	System	31 Dec 2020 20:26:50

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26

US3432617

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26

US3432617

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:46

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'No (N)'	(b) (4), (b) (6)	31 Dec 2020 20:27:03

US3432617

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 20:27:03

US3432617

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Dec 2020 20:28:33

US3432617

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31DEC2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under OL-1 in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 06:44:13
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31DEC2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under OL-1 in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' answered with 'again, in PPD. 1F60N37' (Site from DM).	Monica Feeley (b) (4)	12 Mar 2021 21:44:59
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31DEC2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under OL-1 in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 15:06:03
User entered '31 Dec 2020'	(b) (4), (b) (6)	31 Dec 2020 20:28:33

US3432617

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered '14:45'	(b) (4), (b) (6)	31 Dec 2020 20:28:33

US3432617

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '31 Dec 2020 14:45'	System	31 Dec 2020 20:28:33

US3432617

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Dec 2020 20:28:38

US3432617

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered '1'	System	31 Dec 2020 20:28:38

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[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 (91753b5592a4b4aa)', Time: '2020-12-28T16:46:57', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '0b335c0b-fa2a-45c9-b2f5-5fab7afe54ee'	System	28 Dec 2020 21:47:35
User entered 'Yes (Y)'	System	28 Dec 2020 21:47:35

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Have you been exposed to someone with 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 (91753b5592a4b4aa)', Time: '2020-12-28T16:47:03', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '0b335c0b-fa2a-45c9-b2f5-5fab7afe54ee'	System	28 Dec 2020 21:47:35
User entered 'No (N)'	System	28 Dec 2020 21:47:35

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[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 (91753b5592a4b4aa)', Time: '2020-12-28T16:47:08', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '0b335c0b-fa2a-45c9-b2f5-5fab7afe54ee'	System	28 Dec 2020 21:47:35
User entered 'No (N)'	System	28 Dec 2020 21:47:35

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

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 (91753b5592a4b4aa)', Time: '2020-12-28T16:47:14', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '0b335c0b-fa2a-45c9-b2f5-5fab7afe54ee'	System	28 Dec 2020 21:47:35
User entered 'Yes (Y)'	System	28 Dec 2020 21:47:35

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Please 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 (91753b5592a4b4aa)', Time: '2020-12-28T16:47:18', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '0b335c0b-fa2a-45c9-b2f5-5fab7afe54ee'	System	28 Dec 2020 21:47:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 21:47:35

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2020-12-28T16:47:21', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '0b335c0b-fa2a-45c9-b2f5-5fab7afe54ee' User entered '28 Dec 2020 16:47:21'	System	28 Dec 2020 21:47:35
	System	28 Dec 2020 21:47:35

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[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 (91753b5592a4b4aa)', Time: '2021-01-08T14:49:56', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '5998be47-e4a6-49cb-8e93-4d9ab859fa34'	System	08 Jan 2021 19:50:10
User entered 'No (N)'	System	08 Jan 2021 19:50:10

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Have you been exposed to someone with 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 (91753b5592a4b4aa)', Time: '2021-01-08T14:50:00', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '5998be47-e4a6-49cb-8e93-4d9ab859fa34'	System	08 Jan 2021 19:50:10
User entered 'No (N)'	System	08 Jan 2021 19:50:10

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91753b5592a4b4aa)', Time: '2021-01-08T14:50:03', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '5998be47-e4a6-49cb-8e93-4d9ab859fa34'	System	08 Jan 2021 19:50:10
User entered '08 Jan 2021 14:50:03'	System	08 Jan 2021 19:50:10

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[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 (ea83801530f1e96c)', Time: '2021-02-11T15:58:14', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'bf0b47e3-aa3c-4530-9b78-29fa86a180f4'	System	11 Feb 2021 20:58:35
User entered 'No (N)'	System	11 Feb 2021 20:58:35

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Have you been exposed to someone with 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 (ea83801530f1e96c)', Time: '2021-02-11T15:58:27', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'bf0b47e3-aa3c-4530-9b78-29fa86a180f4'	System	11 Feb 2021 20:58:35
User entered 'No (N)'	System	11 Feb 2021 20:58:35

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea83801530f1e96c)', Time: '2021-02-11T15:58:30', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'bf0b47e3-aa3c-4530-9b78-29fa86a180f4'	System	11 Feb 2021 20:58:35
User entered '11 Feb 2021 15:58:30'	System	11 Feb 2021 20:58:35

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[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 (ea83801530f1e96c)', Time: '2021-02-18T01:00:30', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '5638db08-51a6-4713-adf5-0940e8dc4564'	System	18 Feb 2021 06:00:43
User entered 'No (N)'	System	18 Feb 2021 06:00:43

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Have you been exposed to someone with 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 (ea83801530f1e96c)', Time: '2021-02-18T01:00:33', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '5638db08-51a6-4713-adf5-0940e8dc4564'	System	18 Feb 2021 06:00:43
User entered 'No (N)'	System	18 Feb 2021 06:00:43

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea83801530f1e96c)', Time: '2021-02-18T01:00:36', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '5638db08-51a6-4713-adf5-0940e8dc4564'	System	18 Feb 2021 06:00:43
User entered '18 Feb 2021 01:00:36'	System	18 Feb 2021 06:00:43

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[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 (ea83801530f1e96c)', Time: '2021-02-25T22:08:24', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '5703ca6c-f3a3-4dce-b617-33d516434818'	System	26 Feb 2021 03:14:16
User entered 'No (N)'	System	26 Feb 2021 03:14:16

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Have you been exposed to someone with 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 (ea83801530f1e96c)', Time: '2021-02-25T22:08:27', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '5703ca6c-f3a3-4dce-b617-33d516434818'	System	26 Feb 2021 03:14:16
User entered 'No (N)'	System	26 Feb 2021 03:14:16

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea83801530f1e96c)', Time: '2021-02-25T22:08:30', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '5703ca6c-f3a3-4dce-b617-33d516434818'	System	26 Feb 2021 03:14:16
User entered '25 Feb 2021 22:08:30'	System	26 Feb 2021 03:14:16

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[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 (ea83801530f1e96c)', Time: '2021-03-05T11:52:24', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f6948e99-ca07-492b-94b8-b0d63371c3e6'	System	05 Mar 2021 16:59:36
User entered 'No (N)'	System	05 Mar 2021 16:59:36

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Have you been exposed to someone with 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 (ea83801530f1e96c)', Time: '2021-03-05T11:59:26', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f6948e99-ca07-492b-94b8-b0d63371c3e6'	System	05 Mar 2021 16:59:36
User entered 'No (N)'	System	05 Mar 2021 16:59:36

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea83801530f1e96c)', Time: '2021-03-05T11:59:30', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'f6948e99-ca07-492b-94b8-b0d63371c3e6'	System	05 Mar 2021 16:59:36
User entered '05 Mar 2021 11:59:30'	System	05 Mar 2021 16:59:36

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[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 (ea83801530f1e96c)', Time: '2021-03-11T00:17:53', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '1dd9a61a-a254-4989-945a-a489615028d3'	System	11 Mar 2021 05:18:02
User entered 'No (N)'	System	11 Mar 2021 05:18:02

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Have you been exposed to someone with 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 (ea83801530f1e96c)', Time: '2021-03-11T00:17:57', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '1dd9a61a-a254-4989-945a-a489615028d3'	System	11 Mar 2021 05:18:02
User entered 'No (N)'	System	11 Mar 2021 05:18:02

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea83801530f1e96c)', Time: '2021-03-11T00:18:00', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '1dd9a61a-a254-4989-945a-a489615028d3'	System	11 Mar 2021 05:18:02
User entered '11 Mar 2021 00:18:00'	System	11 Mar 2021 05:18:02

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[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 (ea83801530f1e96c)', Time: '2021-03-20T08:01:02', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '62d63b6c-f1f0-4dd2-bde5-a1d579632dc8'	System	20 Mar 2021 12:01:10
User entered 'No (N)'	System	20 Mar 2021 12:01:10

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Have you been exposed to someone with 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 (ea83801530f1e96c)', Time: '2021-03-20T08:01:04', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '62d63b6c-f1f0-4dd2-bde5-a1d579632dc8'	System	20 Mar 2021 12:01:10
User entered 'No (N)'	System	20 Mar 2021 12:01:10

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea83801530f1e96c)', Time: '2021-03-20T08:01:06', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '62d63b6c-f1f0-4dd2-bde5-a1d579632dc8'	System	20 Mar 2021 12:01:10
User entered '20 Mar 2021 08:01:06'	System	20 Mar 2021 12:01:10

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[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 (ea83801530f1e96c)', Time: '2021-03-25T00:37:35', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e4ff5b1d-4835-4e46-a282-56766ac758a1'	System	25 Mar 2021 04:37:47
User entered 'No (N)'	System	25 Mar 2021 04:37:47

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Have you been exposed to someone with 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 (ea83801530f1e96c)', Time: '2021-03-25T00:37:38', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e4ff5b1d-4835-4e46-a282-56766ac758a1'	System	25 Mar 2021 04:37:47
User entered 'No (N)'	System	25 Mar 2021 04:37:47

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea83801530f1e96c)', Time: '2021-03-25T00:37:41', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'e4ff5b1d-4835-4e46-a282-56766ac758a1' User entered '25 Mar 2021 00:37:41'	System	25 Mar 2021 04:37:47
	System	25 Mar 2021 04:37:47

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[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 (ea83801530f1e96c)', Time: '2021-04-11T11:56:21', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'a592e07e-31d7-491e-a092-bca6678fff60'	System	11 Apr 2021 15:56:31
User entered 'No (N)'	System	11 Apr 2021 15:56:31

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Have you been exposed to someone with 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 (ea83801530f1e96c)', Time: '2021-04-11T11:56:24', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'a592e07e-31d7-491e-a092-bca6678fff60'	System	11 Apr 2021 15:56:31
User entered 'No (N)'	System	11 Apr 2021 15:56:31

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea83801530f1e96c)', Time: '2021-04-11T11:56:28', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: 'a592e07e-31d7-491e-a092-bca6678fff60'	System	11 Apr 2021 15:56:31
User entered '11 Apr 2021 11:56:28'	System	11 Apr 2021 15:56:31

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[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 (ea83801530f1e96c)', Time: '2021-04-15T01:01:08', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '61b349c6-bd68-4b43-a787-78639cff3b4a'	System	15 Apr 2021 05:01:17
User entered 'No (N)'	System	15 Apr 2021 05:01:17

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

Have you been exposed to someone with 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 (ea83801530f1e96c)', Time: '2021-04-15T01:01:11', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '61b349c6-bd68-4b43-a787-78639cff3b4a'	System	15 Apr 2021 05:01:17
User entered 'No (N)'	System	15 Apr 2021 05:01:17

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea83801530f1e96c)', Time: '2021-04-15T01:01:14', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '61b349c6-bd68-4b43-a787-78639cff3b4a'	System	15 Apr 2021 05:01:17
User entered '15 Apr 2021 01:01:14'	System	15 Apr 2021 05:01:17

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 13:10:12

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:10:12

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '24 Nov 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '28 Nov 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '01 Dec 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '05 Dec 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '08 Dec 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '12 Dec 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '15 Dec 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '19 Dec 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '22 Dec 2022 00:01'	System	20 Nov 2020 13:10:12

US3432617

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:12
Amendment Manager: User entered '26 Dec 2022 23:59'	System	20 Nov 2020 13:10:12

US3432617

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:40:46

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 06:24:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea83801530f1e96c)', Time: '2021-02-28T02:53:38', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '8aefde54-7f4d-4f48-a07c-f064a7847c4c'	System	28 Feb 2021 07:53:47
User entered 'No (N)'	System	28 Feb 2021 07:53:47

US3432617

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:40:46

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:24:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea83801530f1e96c)', Time: '2021-02-28T02:53:45', User OID: 'PatientReportedOutcome (US3432617)', ODM File OID: '8aefde54-7f4d-4f48-a07c-f064a7847c4c' User entered '28 Feb 2021 02:53:45'	System	28 Feb 2021 07:53:47
	System	28 Feb 2021 07:53:47

US3432617

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Yes (Y)'	Bethany Evans (b) (4)	01 Feb 2021 19:14:20

US3432617

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered '29 Jan 2021'	Bethany Evans (b) (4)	01 Feb 2021 19:14:20

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Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Contact Not Made (CONTACT NOT MADE)'	Bethany Evans (b) (4)	01 Feb 2021 19:14:20

US3432617

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:33:15
User entered 'Pt was unable to be reached for safety call. Pt was called 1/25 at 12:06, 1/25 at 16:18, 1/27 at 11:53 and 1/29 at 12:58.'	Bethany Evans (b) (4)	01 Feb 2021 19:14:20

US3432617

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	31 Mar 2021 20:31:11

US3432617

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:26
User entered 'I'	System	31 Mar 2021 20:31:11

US3432617

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	31 Mar 2021 20:34:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Cauley (b) (4)	31 Mar 2021 20:34:02
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	31 Mar 2021 20:33:53
User entered 'No (N)'	Jessica Cauley (b) (4)	31 Mar 2021 20:33:53

US3432617

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered '4 Mar 2021'	Jessica Cauley (b) (4)	31 Mar 2021 20:33:53

US3432617

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jessica Cauley (b) (4)	31 Mar 2021 20:33:53

US3432617

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'multiple attempts to contact participant. study team left voicemails. no contact made'	Jessica Cauley (b) (4)	31 Mar 2021 20:33:53

US3432617

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:36
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	31 Mar 2021 20:34:05

US3432617

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:36
User entered 'I'	System	31 Mar 2021 20:34:05

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:40:46

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '18 Nov 2020'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:38:26

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Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:40:46

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '16:00'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:38:26

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:40:46

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:38
User entered '18 Nov 2020 16:00'	System	18 Nov 2020 23:38:26

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:40:46

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Clinic Visit - Scheduled (Clinic Visit - Jun Bai Park Chang Scheduled)'	(b) (4)	18 Nov 2020 23:38:26

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:40:46

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:38:26

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Day 1 (Day 1)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '12 Nov 2020'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '0'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User entered '%'	System	18 Nov 2020 23:39:07

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:40:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Day 2 (Day 2)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '13 Nov 2020'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '0'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User entered '%'	System	18 Nov 2020 23:39:49

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:40:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:39:49

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Day 3 (Day 3)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '14 Nov 2020'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '0'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User entered '%'	System	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:40:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:13

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Day 4 (Day 4)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '15 Nov 2020'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '0'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User entered '%'	System	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Moderate (Moderate)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:40:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:40:37

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Day 5 (Day 5)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '16 Nov 2020'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '0'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User entered '%'	System	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Moderate (Moderate)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:40:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:04

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Day 6 (Day 6)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '17 Nov 2020'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '0'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User entered '%'	System	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Moderate (Moderate)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:40:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:41:27

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Day 7 (Day 7)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '18 Nov 2020'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '0'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '99'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User entered '%'	System	18 Nov 2020 23:42:35

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '97.5' F	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Moderate (Moderate)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:40:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:42:35

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Day 8 (Day 8)'	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '19 Nov 2020'	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '1'	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User entered empty.	System	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:40:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:06

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Day 9 (Day 9)'	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '20 Nov 2020'	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '1'	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User entered empty.	System	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:40:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:20

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Day 10 (Day 10)'	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '21 Nov 2020'	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '1'	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User entered empty.	System	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:40:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:18:32

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Day 11 (Day 11)'	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '22 Nov 2020'	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '1'	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User entered empty.	System	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:40:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:10

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Day 12 (Day 12)'	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '23 Nov 2020'	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '1'	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User entered empty.	System	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:40:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Day 13 (Day 13)'	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '24 Nov 2020'	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '1'	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User entered empty.	System	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:40:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:48
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:19:34

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:40:46

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '18 Nov 2020'	Austin Kim (b) (4)	24 Nov 2020 22:21:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:40:46

[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 10:01:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	Austin Kim (b) (4)	24 Nov 2020 22:21:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:40:46

[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 10:01:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'No (N)'	Austin Kim (b) (4)	24 Nov 2020 22:21:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:40:46

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '18 Nov 2020'	Austin Kim (b) (4)	24 Nov 2020 22:21:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:40:46

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Austin Kim (b) (4)	24 Nov 2020 22:21:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:40:46

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:21:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:40:46

[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 10:01:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'No (N)'	Austin Kim (b) (4)	24 Nov 2020 22:21:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:40:46

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:21:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:40:46

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:21:22

US3432617

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:40:46

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:55
User entered '0'	System	24 Nov 2020 22:21:22

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:40:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User accepted default value 'Day 3 (Day 3)'	Austin Kim (b) (4) (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:40:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'Yes (Y)'	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:40:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered '20 Nov 2020'	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:40:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User accepted default value 'Day 5 (Day 5)'	Austin Kim (b) (4) (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:40:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'Yes (Y)'	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:40:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered '23 Nov 2020'	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:40:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User accepted default value 'Day 7 (Day 7)'	Austin Kim (b) (4) (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:40:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:40:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered empty.	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:40:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User accepted default value 'Day 9 (Day 9)'	Austin Kim (b) (4) (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:40:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:40:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered empty.	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:40:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User accepted default value 'Day 14 (Day 14)'	Austin Kim (b) (4) (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:40:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:40:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered empty.	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:40:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User accepted default value 'Day 21 (Day 21)'	Austin Kim (b) (4) (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:40:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:40:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered empty.	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:40:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User accepted default value 'Day 28 (Day 28)'	Austin Kim (b) (4) (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:40:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'NA (COVID-19 Negative) (NA)'	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:40:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered empty.	Austin Kim (b) (4)	12 Mar 2021 15:14:35

US3432617

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:45:04

US3432617

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,23NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 06:40:40
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,23NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'saliva log updated' (Site from DM).	Austin Kim (b) (4) (b) (4)	12 Mar 2021 15:14:45
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,23NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:08:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '18 Nov 2020'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:45:04

US3432617

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[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 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Clinic (Clinic)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:45:04

US3432617

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User entered 'SICKD1'	System	18 Nov 2020 23:45:04

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '18 Nov 2020'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '16:18'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User entered '18 Nov 2020 16:18'	System	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang	18 Nov 2020 23:45:44
DataPoint set to visible.	(b) (4) System	18 Nov 2020 23:45:04

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered missing code ND - Not Done.	Jun Bai Park Chang	18 Nov 2020 23:45:44
DataPoint set to visible.	(b) (4) System	18 Nov 2020 23:45:04

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '97.5' F	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Other (Other)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'infrared'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '93'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User entered 'bpm'	System	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '12'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User entered 'breaths/min'	System	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '111'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User entered 'mmHg'	System	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 15:01:28
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:50:57
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		18 Nov 2020 23:45:44
User entered '58'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User entered 'mmHg'	System	18 Nov 2020 23:45:44

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47

US3432617

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47

US3432617

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:51:02

US3432617

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '18 Nov 2020'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:51:02

US3432617

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:40:46

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User closed query 'please complete the saliva sample log' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 23:10:01
Query 'please complete the saliva sample log' answered with 'saliva log updated' (Site from CRA).	Austin Kim (b) (4)	12 Mar 2021 15:15:04
User opened query 'please complete the saliva sample log' (Site from CRA).	(b) (4)	
User opened query 'please complete the saliva sample log' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 23:44:17
User entered 'Yes (Y)'	Jun Bai Park Chang	18 Nov 2020 23:51:29
	(b) (4)	

US3432617

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:40:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:47
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered '18 Nov 2020'	Jun Bai Park Chang (b) (4)	18 Nov 2020 23:51:29

US3432617

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Dec 2020 21:43:35

US3432617

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 31-DEC-2020 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:45:55
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 31-DEC-2020 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' answered with 'Updated. The sample collection date is confirmed to be 31DEC2021.' (Site from DM).	Tenaizus Woods (b) (4)	22 Mar 2021 16:41:36
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 31-DEC-2020 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 12:11:43
User entered '31 Dec 2020'	(b) (4), (b) (6)	31 Dec 2020 21:43:35

US3432617

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	31 Dec 2020 21:43:35

US3432617

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered 'UNBLND_DECIDE'	System	31 Dec 2020 21:43:35

US3432617

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:46

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '31 Dec 2020'	(b) (4), (b) (6)	31 Dec 2020 21:43:49

US3432617

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:46

[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 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered '0'	Monica Feeley (b) (4)	08 Mar 2021 21:21:55
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 09:54:54

US3432617

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:46

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Dec 2020 21:43:49

US3432617

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:46

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'Amendment 6 or later (Amendment 6 or later)'	Monica Feeley (b) (4)	08 Mar 2021 21:21:55
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:54:54

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:46

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '31 Dec 2020'	(b) (4), (b) (6)	31 Dec 2020 21:43:49

US3432617

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:46

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	31 Dec 2020 21:43:49

US3432617

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:46

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 05:18:24
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	31 Dec 2020 21:43:49

US3432617

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:46

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 05:18:24
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	31 Dec 2020 21:43:49

US3432617

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:46

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
Signature has been broken.	Monica Feeley (b) (4)	08 Mar 2021 21:26:01
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	08 Mar 2021 21:26:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Dec 2020 21:43:49

US3432617

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:46

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered '1'	System	31 Dec 2020 21:43:49

US3432617

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:46

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered empty.	System	08 Mar 2021 21:26:01
User entered '1'	System	31 Dec 2020 21:43:49

US3432617

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'Yes (Y)'	Monica Feeley (b) (4)	08 Mar 2021 21:25:10

US3432617

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered '31 Dec 2020'	Monica Feeley (b) (4)	08 Mar 2021 21:25:10

US3432617

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered '14:45'	Monica Feeley (b) (4)	08 Mar 2021 21:25:10

US3432617

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered '31 Dec 2020 14:45'	System	08 Mar 2021 21:25:10

US3432617

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered 'Yes (Y)'	Monica Feeley (b) (4)	08 Mar 2021 21:25:23

US3432617

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered '31 Dec 2020'	Monica Feeley (b) (4)	08 Mar 2021 21:25:23

US3432617

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
User entered '14:50'	Monica Feeley (b) (4)	08 Mar 2021 21:25:23

US3432617

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:38
User entered '31 Dec 2020 14:50'	System	08 Mar 2021 21:25:23

US3432617

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:40:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	27 Oct 2020 16:53:01

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User closed query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:27:44
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermal and epidermal conditions NEC, PT: Papule, LLT: Papule - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 04:14:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 04:14:00
Data point term sent to Coder	System	07 Apr 2021 23:00:17
Query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Natalie Izaguirre (b) (4) (b) (4)	07 Apr 2021 22:59:50
Coding entries removed.	Natalie Izaguirre (b) (4) (b) (4)	07 Apr 2021 22:59:43
User entered 'ERYTHEMATOUS PAPULE (MID-STERNAL, non-urticarial)' reason for change: Data Entry Error	Natalie Izaguirre (b) (4) (b) (4)	07 Apr 2021 22:59:43
User opened query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Dec 2020 10:28:35
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermal and epidermal conditions NEC, PT: Papule, LLT: Papule - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:15:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:15:37
Data point term sent to Coder	System	27 Oct 2020 16:57:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'ERYTHEMATOUS PAPULE (mid-sternal)' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	27 Oct 2020 16:56:19
Data point term sent to Coder	System	27 Oct 2020 16:55:08
User entered 'erythematous papule'	Phoebe Cunningham (b) (4)	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[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 11:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '22 Oct 2020'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:54:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Not Related (NOT RELATED)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Not Related (NOT RELATED)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'None (NONE)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '1'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

US3432617

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

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 11:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:54:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	27 Oct 2020 16:54:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	27 Oct 2020 16:54:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User closed query 'For coding purposes, please split VOMITING/ABDOMINAL PAIN into separate entries.' (Site from Coder).	(b) (4), (b) (6)	08 Mar 2021 18:47:29
User coded data point as SOC: Infections and infestations, HLG: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Gastroenteritis, LLT: Gastroenteritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 20:24:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 20:24:27
Data point term sent to Coder	System	04 Feb 2021 20:23:16
Query 'For coding purposes, please split VOMITING/ABDOMINAL PAIN into separate entries.' answered with 'AE term updated, matches CRF' (Site from Coder).	(b) (4), (b) (6)	04 Feb 2021 20:22:35
User entered 'GASTROENTERITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 20:22:23
Coding entries removed.	(b) (4), (b) (6)	04 Feb 2021 20:22:16
User entered 'Gastroenteritis ga' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 20:22:16
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 11:06:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 11:06:15
User opened query 'For coding purposes, please split VOMITING/ABDOMINAL PAIN into separate entries.' (Site from Coder).	(b) (4), (b) (6)	29 Dec 2020 11:05:53
Data point term sent to Coder	System	29 Dec 2020 00:14:13
User entered 'Vomiting/Abdominal Pain'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'No (N)'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'No (N)'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'No (N)'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '23 Dec 2020'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User entered empty.	System	29 Dec 2020 00:13:25

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'No (N)'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '25 Dec 2020'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User entered empty.	System	29 Dec 2020 00:13:25

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'No (N)'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

US3432617

Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:13:25

US3432617

Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 23:53:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 23:53:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	04 Feb 2021 23:53:01
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 00:13:25
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 23:53:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 23:53:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	04 Feb 2021 23:53:01
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 00:13:25
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 23:53:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 23:53:01
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	04 Feb 2021 23:53:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Dec 2020 00:13:25
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 05:43:54
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:25:14
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 06:43:16
User entered '1'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User entered '0'	System	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06
User entered '0'	System	29 Dec 2020 00:13:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:46:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:28:51
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:28:27
	[REDACTED]	
User entered 'USA-US078-2021-mRNA-1273-P301000014'	System	05 Feb 2021 17:28:21
User entered 'New'	(b) (4), (b) (6)	05 Feb 2021 17:28:21
	[REDACTED]	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:28:51
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug dependence, LLT: Drug addiction - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 14:41:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 14:41:57
User closed query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 10:12:10
Data point term sent to Coder	System	08 Mar 2021 21:20:23
Query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' answered with 'this has been updated to "opiod detox for drug detox"' (Site from DM).	Monica Feeley (b) (4)	08 Mar 2021 21:19:52
Coding entries removed.	Monica Feeley (b) (4)	08 Mar 2021 21:19:33
User entered 'OPIOID DETOX for drug addiction' reason for change: Per Query Resolution	Monica Feeley (b) (4)	08 Mar 2021 21:19:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Drug withdrawal therapies, PT: Drug withdrawal maintenance therapy, LLT: Opioid maintenance treatment - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 23:45:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 23:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' (Site from DM). Data point term sent to Coder	(b) (4), (b) (6)	23 Feb 2021 01:36:10
User entered 'Opioid detox'	System Xhoi Mitre (b) (4) (b) (4)	04 Feb 2021 23:59:48 04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered 'No (N)'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:28:51
	[REDACTED]	
User entered 'No (N)'	Xhoi Mitre (b) (4)	04 Feb 2021 23:59:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered '10 Jan 2021'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered empty.	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:28:51
	[REDACTED]	
User entered 'No (N)'	Xhoi Mitre (b) (4)	04 Feb 2021 23:59:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered '3 Feb 2021'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:28:51
	[REDACTED]	
User entered empty.	Xhoi Mitre (b) (4)	04 Feb 2021 23:59:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

US3432617

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

US3432617

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered '0'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

US3432617

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered '0'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

US3432617

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered '1'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered '10 Jan 2021'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

US3432617

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered '3 Feb 2021'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

US3432617

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered 'No (N)'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered empty.	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered '0'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered '0'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered '0'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:28:51
User closed query 'PV Query: As the last dose of study drug was given on 02-Dec-2020, please update the action taken with placebo from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 13:38:02
Query 'PV Query: As the last dose of study drug was given on 02-Dec-2020, please update the action taken with placebo from none to not applicable.' answered with 'this has been updated' (Site from Safety).	Monica Feeley (b) (4)	08 Mar 2021 21:17:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Monica Feeley (b) (4)	08 Mar 2021 21:17:11
User opened query 'PV Query: As the last dose of study drug was given on 02-Dec-2020, please update the action taken with placebo from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 15:59:46
User entered 'None (NONE)'	Xhoi Mitre (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

None

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User closed query 'Per CDM re-query: Thank you for the information. Please retrieve the information from the subject and update the CON MED / CON PROC as appropriate. For tracking purpose, please leave the query open till the information available. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:27:58
Query 'Per CDM re-query: Thank you for the information. Please retrieve the information from the subject and update the CON MED / CON PROC as appropriate. For tracking purpose, please leave the query open till the information available. ' answered with 'we are unable to obtain this information from the participant. this is confirmed. ' (Site from DM). DataPoint Verified.	Monica Feeley (b) (4)	07 Apr 2021 23:04:50
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 18:28:51
User opened query 'Per CDM re-query: Thank you for the information. Please retrieve the information from the subject and update the CON MED / CON PROC as appropriate. For tracking purpose, please leave the query open till the information available. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 05:59:18
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'we have not received any information at the moment regarding medications/procedures, so we have marked this as none' (Site from DM).	Monica Feeley (b) (4)	11 Mar 2021 05:59:16
	(b) (4)	08 Mar 2021 21:28:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

None

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 01:35:54
Query 'PV Query: As the last dose of study drug was given on 02-Dec-2020, please update the action taken with placebo from none to not applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 15:59:36
User opened query 'PV Query: As the last dose of study drug was given on 02-Dec-2020, please update the action taken with placebo from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 15:53:43
User entered '1'	Xhoi Mitre (b) (4) (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
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 or the information is not expected to be obtained, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 18:09:03
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 or the information is not expected to be obtained, please state so. ' answered with 'we are unable to obtain this information from this participant, this is confirmed' (Site from Safety). DataPoint Verified.	Monica Feeley (b) (4)	07 Apr 2021 23:05:09
	(b) (4), (b) (6)	16 Mar 2021 18:28:51
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 or the information is not expected to be obtained, please state so. ' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 13:00:19
User closed query 'PV Query: Thank you for providing the list of concomitant medications. Please confirm if the "breathing inhaler" was prescribed for the albuterol sulfate with the same indication and start date. If not, please provide the generic name/trade name of the concomitant medication which was listed as a 'breathing inhaler'. ' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 13:38:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Thank you for providing the list of Monica Feeley concomitant medications. Please confirm if the "breathing inhaler" was prescribed for the albuterol sulfate with the same indication and start date. If not, please provide the generic name/trade name of the concomitant medication which was listed as a 'breathing inhaler'.' answered with 'albuterol sulfate is the actual name of the breathing inhaler.' (Site from Safety).	(b) (4)	08 Mar 2021 21:27:36
User opened query 'PV Query: Thank you for providing the list of concomitant medications. Please confirm if the "breathing inhaler" was prescribed for the albuterol sulfate with the same indication and start date. If not, please provide the generic name/trade name of the concomitant medication which was listed as a 'breathing inhaler'.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 15:55:08
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	16 Mar 2021 18:28:51
User entered '0'	Xhoi Mitre (b) (4) [REDACTED] (b) (4)	04 Feb 2021 23:59:29

US3432617

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:28:51
	[REDACTED]	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Xhoi Mitre (b) (4)	04 Feb 2021 23:59:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:28:51
	[REDACTED]	
User entered empty.	Xhoi Mitre (b) (4)	04 Feb 2021 23:59:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:28:51
User closed query 'PV Query: Will participant receive mRNA-1273 was checked as 'yes'. Please confirm if the subject received mRNA-1273. If so, please confirm when the subject received it.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 13:39:57
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)	09 Mar 2021 13:39:46
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page).' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 13:39:31
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 'as of right now, we do not have information regarding medical intervention and/or surgical treatments.' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	08 Mar 2021 21:28:51
Query 'PV Query: Will participant receive mRNA-1273 was checked as 'yes'. Please confirm if the subject received mRNA-1273. If so, please confirm when the subject received it.' answered with 'we have updated this to no based on a conversation with the participant' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	08 Mar 2021 21:26:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page).' answered with 'please note that for this SAE we are unable to obtain the medical record due to it being sensitive information' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	08 Mar 2021 21:21:34
User opened query 'PV Query: Will participant receive mRNA-1273 was checked as 'yes'. Please confirm if the subject received mRNA-1273. If so, please confirm when the subject received it.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 15:58:35
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)	12 Feb 2021 15:54:38
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page).' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 15:54:15
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Feb 2021 00:03:48
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Feb 2021 00:03:48
User entered 'participant admitted to rehab facility from 10JAN21 until 03FEB21 for opioid detox' reason for change: Data Entry Error	Xhoi Mitre (b) (4) (b) (4)	05 Feb 2021 00:03:48
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Feb 2021 23:59:29
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	04 Feb 2021 23:59:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 23:59:29

US3432617

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 23:59:29

US3432617

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Feb 2021 23:59:29

US3432617

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Difficulty breathing - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 22:47:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 22:47:24
Data point term sent to Coder	System	07 Apr 2021 22:46:57
User entered 'difficulty breathing'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

US3432617

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

US3432617

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'No (N)'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

US3432617

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'No (N)'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '12 Nov 2020'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User entered empty.	System	07 Apr 2021 22:46:22

US3432617

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'No (N)' reason for change: Data Entry Error	Natalie Izaguirre (b) (4)	07 Apr 2021 22:55:53
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '02 Dec 2020' reason for change: Data Entry Error	Natalie Izaguirre (b) (4)	07 Apr 2021 22:55:53
User entered empty.	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User entered empty.	System	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'No (N)'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

US3432617

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

US3432617

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

US3432617

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

US3432617

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'Not Related (NOT RELATED)'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'Not Related (NOT RELATED)'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'None (NONE)'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '1'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

US3432617

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Natalie Izaguirre (b) (4)	07 Apr 2021 22:55:53
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 22:46:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Apr 2021 22:46:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:31
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 22:46:22
User entered empty.	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

US3432617

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	Natalie Izaguirre (b) (4)	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User entered '0'	System	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51
User entered '1'	System	07 Apr 2021 22:46:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:51

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:40:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 12:50:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	[REDACTED]	
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN OPIOID DEPENDENCE, PRODUCT: BUPRENORPHINE;NALOXONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 14:52:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 14:52:37
Data point term sent to Coder	System	27 Oct 2020 13:03:22
User entered 'buprenorphine/naloxone (8/2mg)'	(b) (4), (b) (6)	27 Oct 2020 13:02:56
	[REDACTED]	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'No (N)'	(b) (4), (b) (6) [REDACTED]	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'drug addiction'	(b) (4), (b) (6) [REDACTED]	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 8/2 mg). ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 08:15:17
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 8/2 mg). ' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	04 Feb 2021 22:57:10
User entered '8/2' reason for change: Data Entry Error	Monica Feeley (b) (4)	04 Feb 2021 22:57:04
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 8/2 mg). ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 10:18:24
User entered '8'	(b) (4), (b) (6)	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'mg (mg)'	(b) (4), (b) (6) [REDACTED]	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	(b) (4), (b) (6) [REDACTED]	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'twice daily (BID)'	(b) (4), (b) (6) [REDACTED]	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	(b) (4), (b) (6) [REDACTED]	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6) [REDACTED]	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	(b) (4), (b) (6) [REDACTED]	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'un Feb 2020'	(b) (4), (b) (6) [REDACTED]	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	(b) (4), (b) (6) [REDACTED]	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User closed query 'Per DM CLR: Please review stop date of this Con med as MH has a stop date indicated. Please check if dates should be reconciled so there is a match. Update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 10:58:37
Query 'Per DM CLR: Please review stop date of this Con med as MH has a stop date indicated. Please check if dates should be reconciled so there is a match. Update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'this medication can still be taken even if the person is not currently actively addicted. it can prevent further addition. date is confirmed' (Site from DM).	Monica Feeley (b) (4) (b) (4)	10 Mar 2021 16:51:37
User opened query 'Per DM CLR: Please review stop date of this Con med as MH has a stop date indicated. Please check if dates should be reconciled so there is a match. Update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 09:22:04
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'No (N)'	(b) (4), (b) (6) [REDACTED]	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 13:02:56

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	[REDACTED]	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN HYDROCHLORIDE, PRODUCTSYNONYM: MELFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:58:38
	[REDACTED]	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:58:38
	[REDACTED]	
Data point term sent to Coder	System	27 Oct 2020 16:57:13
User entered 'Melformin'	Phoebe Cunningham	27 Oct 2020 16:57:11
	(b) (4)	
	[REDACTED]	

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'DM2'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '1000'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'mg (mg)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'twice daily (BID)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'un UNK 2016'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'No (N)'	Phoebe Cunningham (b) (4) [REDACTED]	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:57:11

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN, PRODUCTSYNONYM: NEURONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 16:59:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 16:59:48
Data point term sent to Coder	System	10 Nov 2020 15:24:39
User entered 'Neurontin'	Kathleen Garvey (b) (4)	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'No (N)'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'left shoulder pain'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '300'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'mg (mg)'	Kathleen Garvey (b) (4) (b) (4)	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'twice daily (BID)'	Kathleen Garvey (b) (4) (b) (4)	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Kathleen Garvey (b) (4) (b) (4)	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Oral (ORAL)'	Kathleen Garvey (b) (4) (b) (4)	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '10 Nov 2020'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Yes (Y)'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'No (N)'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 15:24:26

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 22:58:28
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 22:58:28
	(b) (4)	
Data point term sent to Coder	System	04 Feb 2021 22:57:46
Coding entries removed.	Monica Feeley (b) (4)	04 Feb 2021 22:57:46
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 17:15:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 17:15:37
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 15:25:41
User entered 'Bupropion'	Kathleen Garvey (b) (4)	10 Nov 2020 15:25:38
	(b) (4)	

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'No (N)'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User closed query 'Per DM CLR-RQ: Response noted. However, please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:28:12
Query 'Per DM CLR-RQ: Response noted. However, please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated on Med Hx' (Site from DM).	Natalie Izaguirre (b) (4)	07 Apr 2021 22:23:58
User opened query 'Per DM CLR-RQ: Response noted. However, please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 09:23:32
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 08:15:25
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	04 Feb 2021 22:57:51
User entered 'DEPRESsion' reason for change: Data Entry Error	Monica Feeley (b) (4)	04 Feb 2021 22:57:46
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 10:18:35

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

[Indication](#)

Audit	User	Time (GMT)
User entered 'anti-depressant'	Kathleen Garvey (b) (4) (b) (4)	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '150'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'mg (mg)'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'once daily (QD)'	Kathleen Garvey (b) (4) (b) (4)	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Oral (ORAL)'	Kathleen Garvey (b) (4) (b) (4)	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Kathleen Garvey (b) (4) (b) (4)	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '10 Nov 2020'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Yes (Y)'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'No (N)'	Kathleen Garvey (b) (4) [REDACTED]	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 15:25:38

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 23:22:58
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 23:22:58
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 22:25:44
User entered 'Albuterol sulfate'	Austin Kim (b) (4)	24 Nov 2020 22:25:28
	(b) (4)	

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'No (N)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:28:19
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' answered with 'updated on AE Events' (Site from DM).	Natalie Izaguirre (b) (4)	07 Apr 2021 22:49:06
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 06:28:17
User entered 'Difficulty breathing'	Austin Kim (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '2'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'puff (PUFF)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'once daily (QD)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '12 Nov 2020'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Yes (Y)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'No (N)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 22:25:28

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: VITAMINS, OTHER COMBINATIONS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Dec 2020 23:05:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Dec 2020 23:05:26
Data point term sent to Coder Coding entries removed.	System Kathleen Garvey (b) (4)	09 Dec 2020 21:11:42 09 Dec 2020 21:11:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 22:36:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 22:36:05
Data point term sent to Coder User entered 'Omega vitamins'	System Austin Kim (b) (4)	24 Nov 2020 22:27:46 24 Nov 2020 22:27:45

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'Yes (Y)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:27:45

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	[REDACTED]	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 21:11:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 21:11:10
User entered 'prophylaxis' reason for change: New Information	Kathleen Garvey (b) (4)	09 Dec 2020 21:11:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 22:27:45
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:27:45
	(b) (4)	

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 21:11:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 21:11:10
User entered '1' reason for change: New Information	Kathleen Garvey (b) (4) (b) (4)	09 Dec 2020 21:11:10
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 22:27:45
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:27:45

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 21:11:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 21:11:10
User entered 'Other (OTHER)' reason for change: New Information	Kathleen Garvey (b) (4) (b) (4)	09 Dec 2020 21:11:10
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 22:27:45
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:27:45

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered 'tablet' reason for change: New Information	Kathleen Garvey (b) (4) [REDACTED]	09 Dec 2020 21:11:10
User entered empty.	Austin Kim (b) (4) [REDACTED]	24 Nov 2020 22:27:45

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	[REDACTED]	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 21:11:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 21:11:10
User entered 'once daily (QD)' reason for change: New Information	Kathleen Garvey (b) (4)	09 Dec 2020 21:11:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 22:27:45
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:27:45
	(b) (4)	

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:27:45

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	[REDACTED]	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 21:11:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 21:11:10
User entered 'Oral (ORAL)' reason for change: New Information	Kathleen Garvey (b) (4)	09 Dec 2020 21:11:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 22:27:45
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:27:45
	(b) (4)	

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:27:45

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	[REDACTED]	
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	09 Dec 2020 21:11:10
User entered 'UN Oct 2020' reason for change: New Information	Kathleen Garvey (b) (4)	09 Dec 2020 21:11:10
	(b) (4)	
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	24 Nov 2020 22:27:45
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:27:45
	(b) (4)	

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered '0'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:27:45

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 21:11:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 21:11:10
User entered 'Yes (Y)' reason for change: New Information	Kathleen Garvey (b) (4) (b) (4)	09 Dec 2020 21:11:10
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 22:27:45
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:27:45

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:29:49
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 22:27:45

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
	[REDACTED]	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 21:11:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 21:11:10
User entered 'No (N)' reason for change: New Information	Kathleen Garvey (b) (4)	09 Dec 2020 21:11:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 22:27:45
User entered empty.	Austin Kim (b) (4)	24 Nov 2020 22:27:45
	(b) (4)	

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Dec 2020 21:11:10
User entered empty.	System	24 Nov 2020 22:27:45

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Dec 2020 21:11:10
User entered empty.	System	24 Nov 2020 22:27:45

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Dec 2020 21:11:10
User entered empty.	System	24 Nov 2020 22:27:45

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Mar 2021 17:26:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Mar 2021 17:26:44
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	02 Mar 2021 17:26:37 02 Mar 2021 17:25:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Dec 2020 00:15:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Dec 2020 00:15:30
Data point term sent to Coder User entered 'Ibuprofen'	System (b) (4), (b) (6)	29 Dec 2020 00:15:14 29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'No (N)'	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:51:07
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:25:48
User entered 'Gastroenteritis' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Mar 2021 17:25:44
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 15:28:19
User entered 'AE'	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'UNK'	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 20:39:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Dec 2020 20:39:01
User entered 'Other (OTHER)' reason for change: Per Query Resolution	(b) (4), (b) (6)	31 Dec 2020 20:39:01
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 00:14:22
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'unk' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 20:39:01
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'once (ONCE)'	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '24 Dec 2020'	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'No (N)'	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered '24 Dec 2020'	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:29:49
User entered 'No (N)'	(b) (4), (b) (6)	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User entered empty.	System	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User entered empty.	System	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:03
User entered empty.	System	29 Dec 2020 00:14:22

US3432617

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:40:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:17:08
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	24 Mar 2021 22:03:44

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'USA-US078-2021-MRNA-1273-P301000014'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'Yes (Y)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'Yes (Y)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'Lindsey'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'Baden'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'MA'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'US'	System	05 Feb 2021 17:29:05

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Mar 2021 13:41:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
	[REDACTED]	
User entered '1'	System	05 Feb 2021 17:29:05

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'USA-US078-2021-MRNA-1273-P301000014'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'Yes (Y)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'Yes (Y)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'Lindsey'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'Baden'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'MA'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'US'	System	05 Feb 2021 17:29:05

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Mar 2021 13:41:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
	[REDACTED]	
User entered '1'	System	05 Feb 2021 17:29:05

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:40:46

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '05/Feb/2021 17:29'	System	05 Feb 2021 17:29:05

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:40:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered '1'	(b) (4), (b) (6)	05 Feb 2021 17:29:05

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'USA-US078-2021-MRNA-1273-P301000014'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'Yes (Y)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'Yes (Y)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'No (N)'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'Lindsey'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'Baden'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:29:00
User entered 'MA'	System	05 Feb 2021 17:28:21

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
User entered 'US'	System	05 Feb 2021 17:29:05

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Mar 2021 13:41:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:32:57
	[REDACTED]	
User entered '1'	System	05 Feb 2021 17:29:05

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:40:46

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
	[REDACTED]	
User entered '09/Mar/2021 08:41'	System	09 Mar 2021 13:41:27

US3432617

Folder: SAE USA-US078-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:40:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:17:08
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:30:20
	[REDACTED]	
User entered '1'	(b) (4), (b) (6)	09 Mar 2021 13:41:27
	[REDACTED]	