

US3032337 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:55:34

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US3032337

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 18:20:14

Generated On: 09 Jun 2021 14:55:34

[Participant ID](#)

US3032337

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

US3032337

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 18:20:14

Generated On: 09 Jun 2021 14:55:34

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 25 AUG 2020

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

Folder OID SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 18:20:14

Generated On: 09 Jun 2021 14:55:34

Date of Birth (MMM yyyy)	(b) (6) 2000
Age	20
Age Units	YEARS
Age (Derived)	20
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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3032337

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 18:20:14

Generated On: 09 Jun 2021 14:55:34

Date of Informed Consent (*dd MMM yyyy*) 25 AUG 2020

Month and Year of Informed Consent (derived) AUG 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

US3032337

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 18:20:14

Generated On: 09 Jun 2021 14:55:34

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Condition	HISTORY OF SEIZURES
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:56:11

Generated On: 09 Jun 2021 14:55:34

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 25 AUG 2020

Time of assessment (00:00-23:59) 11:12 (24 HR)

Vital Signs Date and Time (derived) 25 AUG 2020 11:12

Height (xxx.x) 170.2 cm

Weight (xxx.x) 83.9 kg

BMI (xxx.x) 28.96295 kg/m²

BMI units KG/M2

Temperature (xxx.x) ND - Not Done

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) ND - Not Done

Pulse units BPM

Respiratory Rate (xxx) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 18:20:14

Generated On: 09 Jun 2021 14:55:34

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

25 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 18:20:14

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify

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) 28 Sep 2020 18:20:14

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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) 28 Sep 2020 18:20:15

Generated On: 09 Jun 2021 14:55:34

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 25 AUG 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) 02 Nov 2020 22:27:35

Generated On: 09 Jun 2021 14:55:34

What was the date of randomization? (dd MMM yyyy) 25 AUG 2020

What was the participant's randomization number? 107594

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) 14 Oct 2020 19:47:55

Generated On: 09 Jun 2021 14:55:34

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) 14 Oct 2020 19:47:55

Generated On: 09 Jun 2021 14:55:34

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>)	25 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:12 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 11:12
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Oct 2020 19:47:55

Generated On: 09 Jun 2021 14:55:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	25 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:41 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 12:41
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	85 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 18:20:15

Generated On: 09 Jun 2021 14:55:34

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

25 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 18:20:15

Generated On: 09 Jun 2021 14:55:34

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) 25 AUG 2020

What was the treatment time? (00:00-23:59) 12:08 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 12:08

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) 28 Sep 2020 18:20:15

Generated On: 09 Jun 2021 14:55:34

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 25 AUG 2020

Collection time (*00:00-23:59*) 11:37 (24 HR)

Collection date and time (derived) 25 AUG 2020 11:37

US3032337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 18:20:14

Generated On: 09 Jun 2021 14:55:34

Collection date (<i>dd MMM yyyy</i>)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:32	25 AUG 2020 11:32
Nasopharyngeal Swab 2	No		

US3032337

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:20:15

Generated On: 09 Jun 2021 14:55:34

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 14:55:34

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 98.6 °F

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

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

PC Time Stamp 25 AUG 2020 12:42

PC Open Date & Time 25 AUG 2020 12:28

PC Close Date & Time 25 AUG 2020 14:58

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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 99.4 °F

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

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

PC Time Stamp 25 AUG 2020 23:23
PC Open Date & Time 25 AUG 2020 15:53
PC Close Date & Time 26 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

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	98.6 °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	26 AUG 2020 23:11
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

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 <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	27 AUG 2020 23:02
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °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	29 AUG 2020 10:09
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

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	30 AUG 2020 09:37
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes
No

Please record your **TEMPERATURE** in °F

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

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

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	98.3 °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	31 AUG 2020 18:54
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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	25 AUG 2020 12:42
PC Open Date & Time	25 AUG 2020 12:28
PC Close Date & Time	25 AUG 2020 14:58

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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	25 AUG 2020 23:24
PC Open Date & Time	25 AUG 2020 15:53
PC Close Date & Time	26 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

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	26 AUG 2020 23:11
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

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 AUG 2020 23:02

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

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

29 AUG 2020 10:09

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

30 AUG 2020 09:37

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

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

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

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

31 AUG 2020 18:54

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

No

Yes

PC Time stamp	25 AUG 2020 12:43
PC Open Date & Time	25 AUG 2020 12:28
PC Close Date & Time	25 AUG 2020 14:58

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

No
Yes

PC Time stamp	25 AUG 2020 23:24
PC Open Date & Time	25 AUG 2020 15:53
PC Close Date & Time	26 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

Yes

PC Time stamp	26 AUG 2020 23:11
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

Yes

PC Time stamp	27 AUG 2020 23:03
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

	Yes <input type="checkbox"/>
PC Time stamp	29 AUG 2020 10:09
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

	Yes <input type="checkbox"/>
PC Time stamp	30 AUG 2020 09:37
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

Yes

PC Time stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

	Yes <input type="checkbox"/>
PC Time stamp	31 AUG 2020 18:54
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3032337

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 18:20:14

Generated On: 09 Jun 2021 14:55:34

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 1 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3032337

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:20:14

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 18:20:14

Generated On: 09 Jun 2021 14:55:34

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3032337

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:20:14

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 18:20:14

Generated On: 09 Jun 2021 14:55:34

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3032337

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:20:14

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 18:20:15

Generated On: 09 Jun 2021 14:55:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 18:20:15

Generated On: 09 Jun 2021 14:55:34

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>)	22 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:22 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 12:22
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 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>)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 18:20:15

Generated On: 09 Jun 2021 14:55:34

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>)	22 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:06 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 14:06
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 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>)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3032337

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 18:20:15

Generated On: 09 Jun 2021 14:55:34

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3032337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 18:20:15

Generated On: 09 Jun 2021 14:55:34

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 13:36 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 13:36

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

US3032337

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 18:20:15

Generated On: 09 Jun 2021 14:55:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	22 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:48 (24 HR)
Collection date and time (derived)	22 SEP 2020 12:48

US3032337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 18:20:15

Generated On: 09 Jun 2021 14:55:34

Collection date (<i>dd MMM yyyy</i>)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:37	22 SEP 2020 12:37
Nasopharyngeal Swab 2	No		

US3032337

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:20:15

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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 98.3 °F

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

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

PC Time Stamp 22 SEP 2020 14:06

PC Open Date & Time 22 SEP 2020 13:56

PC Close Date & Time 22 SEP 2020 16:26

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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** 101.6 °F

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

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

PC Time Stamp 22 SEP 2020 23:32
PC Open Date & Time 22 SEP 2020 17:21
PC Close Date & Time 23 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

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	101.6 °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	24 SEP 2020 00:35
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	100.3 °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	24 SEP 2020 13:51
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

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 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

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	97.5 °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 SEP 2020 10:01
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes
No

Please record your **TEMPERATURE** in °F

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 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

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	98.3 °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	29 SEP 2020 06:11
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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	22 SEP 2020 14:07
PC Open Date & Time	22 SEP 2020 13:56
PC Close Date & Time	22 SEP 2020 16:26

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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	22 SEP 2020 23:32
PC Open Date & Time	22 SEP 2020 17:21
PC Close Date & Time	23 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

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	24 SEP 2020 00:36
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

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	24 SEP 2020 13:51
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

27 SEP 2020 10:02

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

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

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

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	29 SEP 2020 06:11
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

No

Yes

PC Time stamp	22 SEP 2020 14:08
PC Open Date & Time	22 SEP 2020 13:56
PC Close Date & Time	22 SEP 2020 16:26

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

No
Yes

PC Time stamp	22 SEP 2020 23:33
PC Open Date & Time	22 SEP 2020 17:21
PC Close Date & Time	23 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

	Yes <input type="checkbox"/>
PC Time stamp	24 SEP 2020 00:36
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

	Yes <input type="checkbox"/>
PC Time stamp	24 SEP 2020 13:52
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

Yes

PC Time stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

	Yes <input type="checkbox"/>
PC Time stamp	27 SEP 2020 10:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

Yes

PC Time stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

	Yes <input type="checkbox"/>
PC Time stamp	29 SEP 2020 06:11
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3032337

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Oct 2020 22:12:18

Generated On: 09 Jun 2021 14:55:34

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3032337

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 01 Oct 2020 22:12:18

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 15:56:11

Generated On: 09 Jun 2021 14:55:34

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 6 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3032337

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:56:11

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Oct 2020 19:47:55

Generated On: 09 Jun 2021 14:55:34

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 13 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3032337

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Oct 2020 19:47:55

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Oct 2020 15:08:45

Generated On: 09 Jun 2021 14:55:34

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 19 OCT 2020

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

Folder OID VISIT3

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Oct 2020 15:08:45

Generated On: 09 Jun 2021 14:55:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:15 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 15:15
Temperature (<i>xxx.x</i>)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032337

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Oct 2020 15:08:45

Generated On: 09 Jun 2021 14:55:34

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3032337

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Oct 2020 15:08:44

Generated On: 09 Jun 2021 14:55:34

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 19 OCT 2020

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

Collection date and time (derived) 19 OCT 2020 15:23

US3032337

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 15:08:44

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	26 OCT 2020 10:01:30
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission 03 NOV 2020 11:47:50

Patient Cloud Open Date & Time 01 NOV 2020 00:01

Patient Cloud Close Date & Time 05 NOV 2020 23:59

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 12:12:52
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 17:59:20
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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 <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	03 DEC 2020 01:44:53
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 08:38:02
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 117

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

No

Yes

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

No

Yes

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

Date and time of submission 17 DEC 2020 09:43:57

Patient Cloud Open Date & Time 17 DEC 2020 00:01

Patient Cloud Close Date & Time 21 DEC 2020 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 DEC 2020 19:38:14
Patient Cloud Open Date & Time	24 DEC 2020 00:01
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US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

01 JAN 2021 12:29:43

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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 09 JAN 2021 12:03:49

Patient Cloud Open Date & Time 07 JAN 2021 00:01

Patient Cloud Close Date & Time 11 JAN 2021 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 145

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

No

Yes

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

No

Yes

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

Date and time of submission 15 JAN 2021 02:12:52

Patient Cloud Open Date & Time 14 JAN 2021 00:01

Patient Cloud Close Date & Time 18 JAN 2021 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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 28 JAN 2021 09:09:41

Patient Cloud Open Date & Time 28 JAN 2021 00:01

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 11:13:31
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	11 FEB 2021 00:02:15
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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	18 FEB 2021 00:04:22
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 187

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

No

Yes

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

No

Yes

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

Date and time of submission 25 FEB 2021 06:17:56

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 194

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

No

Yes

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

No

Yes

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

Date and time of submission 04 MAR 2021 06:43:52

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 201

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

No

Yes

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

No

Yes

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

Date and time of submission 11 MAR 2021 00:02:24

Patient Cloud Open Date & Time 11 MAR 2021 00:01

Patient Cloud Close Date & Time 15 MAR 2021 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 208

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

No

Yes

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

No

Yes

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

Date and time of submission 18 MAR 2021 11:07:35

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	25 MAR 2021 00:02:54
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

Date and time of submission

01 APR 2021 00:02:58

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 APR 2021 03:57:35
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 00:03:05
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 APR 2021 12:06:23
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 250

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

No

Yes

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

No

Yes

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

Date and time of submission 29 APR 2021 00:40:31

Patient Cloud Open Date & Time 29 APR 2021 00:01

Patient Cloud Close Date & Time 03 MAY 2021 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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°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

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:55:34

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 06:44:01

US3032337

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Nov 2020 15:54:03

Generated On: 09 Jun 2021 14:55:34

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3032337

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Nov 2020 15:54:03

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Dec 2020 15:57:09

Generated On: 09 Jun 2021 14:55:34

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3032337

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Dec 2020 15:57:09

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:48:16

Generated On: 09 Jun 2021 14:55:34

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3032337

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:48:16

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:48:16

Generated On: 09 Jun 2021 14:55:34

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 16 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3032337

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:48:16

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 18 MAR 2021

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

Folder OID VISIT4

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3032337

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

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.

US3032337

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 18 MAR 2021

Collection time (*00:00-23:59*) 16:32 (24 HR)

Collection date and time (derived) 18 MAR 2021 16:32

US3032337

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 18:25:54

Generated On: 09 Jun 2021 14:55:34

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3032337

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 18:25:54

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032337

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

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 _____

US3032337

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 07 Jan 2021 19:18:25

Generated On: 09 Jun 2021 14:55:34

Date of Contact	30 DEC 2020
Time of Contact	09:22
Date and Time of Contact (derived)	30 DEC 2020 09:22
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input checked="" type="checkbox"/> Safety Call <input type="checkbox"/> Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

Symptom Day

Day 1	<input checked="" 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 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"/>

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

	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	27 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

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"/>

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

Symptom Day

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

Date	28 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

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)	321 of 2624
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US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

Symptom Day

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

Date	29 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

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

325 of 2624

EAB) (1725)

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

Symptom Day

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

Date 30 DEC 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 36.7 C

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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"/>

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

Date 31 DEC 2020

Assessment Not Done False

O2 Saturation 98 %

O2 Saturation Units %

Temperature 97.5 F

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

333 of 2624

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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"/>

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

	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	1 JAN 2021
------	------------

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

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

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

Temperature	98.6 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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"/>

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

	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	2 JAN 2021
------	------------

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

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

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

Temperature	97.7 F
-------------	--------

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

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

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

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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"/>

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

Date	03 JAN 2021
------	-------------

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

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

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

Temperature	97.3 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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"/>

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

Date 4 JAN 2021

Assessment Not Done False

O2 Saturation 98 %

O2 Saturation Units %

Temperature 97.0 F

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

Symptom Day

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

Date	5 JAN 2021
------	------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

353 of 2624

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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 checked="" 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"/>

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

Date 6 JAN 2021

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 97.7 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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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"/>

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

	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	7 JAN 2021
------	------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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 type="checkbox"/>
Day 13	<input checked="" 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"/>

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

	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	8 JAN 2021
------	------------

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

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

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

Temperature	97.3 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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 type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" 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"/>

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

	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	9 JAN 2021
------	------------

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

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

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

Temperature	97.3 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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 type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" 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"/>

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

	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	10 JAN 2021
------	-------------

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

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

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

Temperature	98.3 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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 type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" 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 30 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

	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	11 JAN 2021
------	-------------

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

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

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

Temperature	97.3 F
-------------	--------

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

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

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

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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 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 checked="" 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 30 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

	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 JAN 2021
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Jan 2021 19:32:09

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 07 Jan 2021 19:18:25

Generated On: 09 Jun 2021 14:55:34

Date of Visit 30 DEC 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 30 DEC 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

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 07 Jan 2021 19:18:25

Generated On: 09 Jun 2021 14:55:34

[Generate Next COVID-19 Assessment](#)

Yes

No

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 12 Feb 2021 19:58:19

Generated On: 09 Jun 2021 14:55:34

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	01 JAN 2021
Day 5	Yes	03 JAN 2021
Day 7	Yes	05 JAN 2021
Day 9	Yes	07 JAN 2021
Day 14	Yes	12 JAN 2021
Day 21	No	
Day 28	No	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 07 Jan 2021 19:18:26

Generated On: 09 Jun 2021 14:55:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 DEC 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

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Jan 2021 19:18:26

Generated On: 09 Jun 2021 14:55:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	13:16 (24 HR)
Vital Signs Date and Time (derived)	30 DEC 2020 13:16
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3032337

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Jan 2021 19:18:26

Generated On: 09 Jun 2021 14:55:34

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

30 DEC 2020

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

US3032337

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 05 Feb 2021 19:42:38

Generated On: 09 Jun 2021 14:55:34

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

30 DEC 2020

US3032337

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

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 18 MAR 2021

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

Folder OID UNBLND_DECIDE

US3032337

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

Form: Unblinding

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Date of updated informed consent (<i>dd MMM yyyy</i>)	18 MAR 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	18 MAR 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	<input type="checkbox"/>
Continuing with mRNA-1273	<input type="checkbox"/>

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 18 MAR 2021

Collection time (*00:00-23:59*) 16:32 (24 HR)

Collection date and time (derived) 18 MAR 2021 16:32

US3032337

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 18 MAR 2021

Collection time (*00:00 - 23:59*) 16:37

Collection Date and Time (derived) 18 MAR 2021 16:37

US3032337

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

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) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

AEID

Adverse event

INTERCRANIAL
SPACE-OCCUPYING LESION
FOUND ON DIAGNOSTIC
IMAGING OF CENTRAL
NERVOUS SYSTEM.

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) 14 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 14 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

	No	<input type="radio"/>
	Unknown	<input type="radio"/>

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>

Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>

Action taken with investigational product	None	<input type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product Withdrawn	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>

Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input checked="" type="radio"/>
	Recovered/Resolved with Sequelae	<input type="radio"/>
	Recovering/Resolving	<input type="radio"/>
	Unknown	<input type="radio"/>

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

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

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

AEID	USA-US032-2021-MRNA-1273-P30 1000011
Adverse event	SEIZURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event True

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 True

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

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

ON 14MAR2021 THE SUBJECT WAS WALKING WHEN HE COLLAPSED AND HIT HIS HEAD. HE HAD A SEIZURE ACTIVITY. TRANSPORTED VIA EMS TO THE HOSPITAL. A CT SCAN REVEALED A BRAIN BLEED, WITH A LESION NOTED ON THAT LOCATION. HE WAS TRANSFERRED TO A LARGER URBAN HOSPITAL, WHERE HE UNDERWENT A BRIEF EVALUATION. HE WAS RELEASED THE SAME DAY AS EVENT. HE DID START ON ANTI SEIZURE MEDICATION. HE ALSO REPORTS HE MAY HAVE HAD AN EPISODE OF LOSING CONSCIOUS ABOUT A WEEK PRIOR TO THIS INCIDENT AS HE HAD A SIMILAR METAL TASTE IN HIS MOUTH WHEN HE AWOKE. UPDATE 23 MAR 2021: MEDICAL RECORDS RECEIVED AND REVIEWED. SUBJECT WAS IN A GAS STATION PARKING LOT AFTER CONTACT WITH THE POLICE. HE REPORTEDLY COLLAPSED AND EXPERIENCED APPROXIMATELY 30 SECONDS OF TONIC-CLONIC SEIZURE ACTIVITY. HE WAS TRANSFERRED TO THE ER VIA AMBULANCE. HE UNDERWENT

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

BLOOD TESTING (NEGATIVE FOR ACUTE CHANGES) AND A CT OF HEAD WITHOUT CONTRAST. THE CT SHOWED A QUESTIONABLE 5 MM AREA OF MINERALIZATION. A 12 LEAD ECG AND TELEMETRY SHOWED SINUS TACHYCARDIA WITH RATES IN 110S CONSISTENT WITH DIAGNOSIS OF SEIZURE. THE SUBJECT WAS GIVEN A ONE TIME BOLUS OF KEPRA AND NS. HE WAS TRANSFERRED TO A LARGE URBAN HOSPITAL FOR FURTHER EVALUATION. IT SHOULD BE NOTED ER REPORTS INDICATE SUBJECT HAS A HX OF SEIZURES, WHICH HAD NOT BEEN NOTED BY SUBJECT DURING PAST VISITS. UPDATE 31MAR2021: MEDICAL RECORDS FROM THE URBAN HOSPITAL ARE REVIEWED. CT OF HEAD OVERREAD BY NEUROLOGISTS AND IS NEGATIVE FOR ACUTE OR CHRONIC CHANGES. NO BLEEDING OR CALCIFICATIONS NOTED. ALSO, BLOOD ALCOHOL LEVEL WAS 74 AT URBAN HOSPITAL, DRUG SCREEN NEGATIVE. CK ELEVATED. WILL FOLLOW-UP OUTPATIENT FOR EEG AT

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

	EPILEPSY CLINIC.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

AEID _____

Adverse event TRAUMATIC HEMORRHAGE OF CEREBRUM, UNSPECIFIED

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) 14 MAR 2021

Start time (00:00-23:59) _____

AE start date and time (derived) _____

Ongoing? Yes No

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

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 (3)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

AEID	
Adverse event	FALL
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

AEID

Adverse event

UPPER RESPIRATORY
INFECTION

Was this a medically-attended AE?

Yes
No

Was this a Solicited Adverse Reaction?

Yes
No

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

Yes
No

Start date (dd MMM yyyy)

27 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)

12 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

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

Is the adverse event serious?

Yes
No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes
No
Unknown

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

AEID

Adverse event

LOSS OF CONSCIOUSNESS

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)

05 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

05 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

AEID

Adverse event

ALCOHOL INTOXICATION
WITHOUT COMPLICATION

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)

14 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

14 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

AEID

Adverse event

SINUS TACHYCARDIA

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)

14 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

14 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 06 Apr 2021 15:46:51

Generated On: 09 Jun 2021 14:55:34

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 06 Nov 2020 17:49:48

Generated On: 09 Jun 2021 14:55:34

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

Yes

No

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

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Name of Medication ACETAMINOPHEN

Prophylaxis Yes
No

Indication SLIGHT INJECTION SITE PAIN

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

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*) 22 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 23 SEP 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

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Name of Medication LEVITIRACETAM

Prophylaxis Yes
No

Indication SEIZURE

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) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

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 checked="" type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 14 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 14 MAR 2021

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

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes
No

Indication SEIZURE

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 (3)

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

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 checked="" type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 14 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 14 MAR 2021

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

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Name of Medication LEVETIRACETAM

Prophylaxis Yes
No

Indication SEIZURE

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 14 MAR 2021

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

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 06 Apr 2021 15:46:52

Generated On: 09 Jun 2021 14:55:34

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 MAR 2021	ELECTROCARDIOGRAM 12-LEAD	Adverse Event	
14 MAR 2021	CT HEAD WITHOUT CONTRAST	Adverse Event	
14 MAR 2021	BASAL METABOLIC PANEL	Adverse Event	
14 MAR 2021	COMPLETE BLOOD COUNT WITH DIFFERENTIAL	Adverse Event	
14 MAR 2021	FINGER STICK GLUCOSE	Adverse Event	
14 MAR 2021	MRI BRAIN WITH WO CONTRAST	Adverse Event	
14 MAR 2021	CT CERVICAL SPINE WO CONTRAST	Adverse Event	
14 MAR 2021	CHEST X-RAY	Adverse Event	
14 MAR 2021	BLOOD ALCOHOL LEVEL	Adverse Event	
14 MAR 2021	CREATINE KINASE	Adverse Event	
14 MAR 2021	DRUGS OF ABUSE SCREEN, URINE	Adverse Event	

US3032337

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:55:34

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

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 14 Apr 2021 19:23:48

Generated On: 09 Jun 2021 14:55:34

SAEID	USA-US032-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 14 Apr 2021 19:23:48

Generated On: 09 Jun 2021 14:55:34

SAEID	USA-US032-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/MAR/2021 09:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 14 Apr 2021 19:23:48

Generated On: 09 Jun 2021 14:55:34

SAEID	USA-US032-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/MAR/2021 06:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 14 Apr 2021 19:23:48

Generated On: 09 Jun 2021 14:55:34

SAEID	USA-US032-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/MAR/2021 10:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 14 Apr 2021 19:23:48

Generated On: 09 Jun 2021 14:55:34

SAEID	USA-US032-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/MAR/2021 12:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) 14 Apr 2021 19:23:48

Generated On: 09 Jun 2021 14:55:34

SAEID	USA-US032-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/APR/2021 06:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (6)

Data signed: (b) (4) 14 Apr 2021 19:23:48

Generated On: 09 Jun 2021 14:55:34

SAEID	USA-US032-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/APR/2021 10:22
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

US3032337 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032337

Form: Participant Creation

Generated On: 09 Jun 2021 14:55:34

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:52:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'US3032337'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 16:19:45

US3032337

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 17:11:54
	(b) (4)	

US3032337

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 16:19:46

US3032337

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 17:11:54

US3032337

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered 'SCRN'	System	25 Aug 2020 17:11:54

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered (b) (6)2000'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 16:19:47

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '20'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:06:18

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered 'YEARS'	System	25 Aug 2020 18:06:18

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered '20'	System	25 Aug 2020 17:12:31

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Male (M)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:06:18
	(b) (4)	

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:20:15
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:06:18

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '1' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	26 Sep 2020 14:56:05
User entered '0' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:08:51
User entered '1'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:06:18

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:06:18
	(b) (4)	

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:06:18
	(b) (4)	

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:06:18
	(b) (4)	

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:06:18
	(b) (4)	

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User closed query 'Per CDM Please note the Race is check as "OTHER" and the option(Hispanic) is same as Ethnicity , kindly clarify or correct.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 05:13:57
Query 'Per CDM Please note the Race is check as "OTHER" and the option(Hispanic) is same as Ethnicity , kindly clarify or correct.' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	26 Sep 2020 14:56:12
User entered '0' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	26 Sep 2020 14:56:05
User opened query 'Per CDM Please note the Race is check as "OTHER" and the option(Hispanic) is same as Ethnicity , kindly clarify or correct.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 04:24:12
User entered '1' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:08:51
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:06:18

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:20:15
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	26 Sep 2020 14:56:05
User entered 'hispanic' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:08:51
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:06:18

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:06:18
	(b) (4)	

US3032337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:34

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:06:18
	(b) (4)	

US3032337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:34

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '25 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 17:12:31
	(b) (4)	

US3032337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered 'Aug 2020'	System	25 Aug 2020 17:12:31

US3032337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered '2020'	System	25 Aug 2020 17:12:31

US3032337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:34

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User closed query 'Per CDM: Protocol Version is recorded as Amendment 4, however to date there is no Amendment 4, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 03:49:48
Query 'Per CDM: Protocol Version is recorded as Amendment 4, however to date there is no Amendment 4, please review and update as appropriate. Thank you.' answered with 'data corrected' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:43:47
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 14:43:31
User opened query 'Per CDM: Protocol Version is recorded as Amendment 4, however to date there is no Amendment 4, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 04:29:24
User entered 'Amendment 4 (4)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:09:47
User entered 'Amendment 2 (2)'	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 17:12:31

US3032337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 17:12:31
	(b) (4)	

US3032337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:34

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 17:12:31
	(b) (4)	

US3032337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 17:12:31
	(b) (4)	

US3032337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 17:12:31
	(b) (4)	

US3032337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 16:19:46

US3032337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered '1'	System	25 Aug 2020 17:12:38

US3032337

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 17:12:38
	(b) (4)	

US3032337

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:55:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Signature has been broken.	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:12:08

US3032337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizures - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 13:39:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 13:39:14
Data point term sent to Coder	System	26 Mar 2021 14:05:07
User entered 'History of Seizures'	Samantha Wieseler (b) (4)	26 Mar 2021 14:05:04

US3032337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'UN UNK 2010'	Samantha Wieseler (b) (4)	26 Mar 2021 14:05:04

US3032337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	Samantha Wieseler (b) (4)	26 Mar 2021 14:05:04

US3032337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:05:04

US3032337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:05:04

US3032337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	Samantha Wieseler (b) (4)	26 Mar 2021 14:05:04

US3032337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered 'Jan 2010'	System	26 Mar 2021 14:05:04

US3032337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered '2010'	System	26 Mar 2021 14:05:04

US3032337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered empty.	System	26 Mar 2021 14:05:04

US3032337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered empty.	System	26 Mar 2021 14:05:04

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:12:51

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '25 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:12:51
	(b) (4)	

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '11:12'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:12:51
	(b) (4)	

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered '25 Aug 2020 11:12'	System	25 Aug 2020 18:12:51

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '170.2' cm	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:12:51
DataPoint set to visible.	(b) (4) System	25 Aug 2020 17:12:38

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '83.9' kg	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:12:51
DataPoint set to visible.	(b) (4) System	25 Aug 2020 17:12:38

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
Amendment Manager: User entered '28.96295'	System	17 Sep 2020 00:01:56
User entered '29.0'	System	25 Aug 2020 18:12:51
DataPoint set to visible.	System	25 Aug 2020 17:12:38

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered 'kg/m2'	System	25 Aug 2020 18:12:51
DataPoint set to visible.	System	25 Aug 2020 17:12:38

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:56:11
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 05:13:20
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:58:56
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:58:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:58:48
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:40:43
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:20:15
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 18:20:49
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	25 Aug 2020 18:20:49

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C reason for change: Data Entry Error	Kelsey Kelley (b) (4)	25 Aug 2020 18:20:49
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 18:12:51
User entered empty.	Kelsey Kelley (b) (4)	25 Aug 2020 18:12:51

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:56:11
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:58:48
User entered empty; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:58:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:12:51

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:12:51
	(b) (4)	

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:56:11
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:58:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:58:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '76'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:12:51

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered 'bpm'	System	25 Aug 2020 18:12:51

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:56:11
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:58:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:58:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:12:51

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered 'breaths/min'	System	25 Aug 2020 18:12:51

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:56:11
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:58:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:58:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '116'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:12:51

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered 'mmHg'	System	25 Aug 2020 18:12:51

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:56:11
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:58:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:58:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '78'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:12:51

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered 'mmHg'	System	25 Aug 2020 18:12:51

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36

US3032337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36

US3032337

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:07

US3032337

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '25 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:09:07

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:09:29

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '1'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:09:29

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29

US3032337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:09:29
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:04:48

US3032337

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '25 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:04:48
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:04:48

US3032337

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'VISIT1'	System	25 Aug 2020 18:04:48

US3032337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 16:54:40

US3032337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:34

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '107594'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 16:54:40

US3032337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 16:54:40

US3032337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:34

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)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:05:05
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:34

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)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:05:05
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:05:05

US3032337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:34

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:05:05

US3032337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:34

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:05:05

US3032337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:34

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	02 Nov 2020 22:27:35
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 09:03:44
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	29 Oct 2020 15:13:09
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	29 Oct 2020 15:13:02
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 12:44:44
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:45:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:50:24

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:47:55
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 06:24:53
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:56:21
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:56:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:56:05
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:55:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:20:15
User entered '170.2' cm	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:47:55
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	13 Oct 2020 13:56:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	13 Oct 2020 13:56:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '83.9' kg	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:47:55
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 06:24:53
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:56:21
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:56:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:56:05
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:55:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:20:15
User entered '170.2' cm	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:47:55
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	13 Oct 2020 13:56:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	13 Oct 2020 13:56:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '83.9' kg	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '25 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:11:48
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '11:12'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '25 Aug 2020 11:12'	System	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 18:20:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	25 Aug 2020 18:20:26
User entered '36.7' C reason for change: Data Entry Error	Kelsey Kelley (b) (4)	25 Aug 2020 18:20:26
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 18:11:48
User entered empty.	System	25 Aug 2020 18:11:48
	Kelsey Kelley (b) (4)	25 Aug 2020 18:11:48
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:11:48
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '76'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'bpm'	System	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'breaths/min'	System	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '116'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'mmHg'	System	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '78'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:11:48
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'mmHg'	System	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:47:55
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 06:24:53
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:56:21
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:56:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:56:05
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:55:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:20:15
User entered '170.2' cm	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:47:55
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	13 Oct 2020 13:56:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	13 Oct 2020 13:56:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '83.9' kg	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:11:48

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:20:26

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:20:26
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '25 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:20:26
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '12:41'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:20:26

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '25 Aug 2020 12:41'	System	25 Aug 2020 18:20:26

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '37.0' C	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:20:26
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:20:26
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:20:26
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '85'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:20:26

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'bpm'	System	25 Aug 2020 18:20:26

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '15'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:20:26

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'breaths/min'	System	25 Aug 2020 18:20:26

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '117'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:20:26

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'mmHg'	System	25 Aug 2020 18:20:26

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '81'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:20:26

US3032337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'mmHg'	System	25 Aug 2020 18:20:26

US3032337

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:34

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:05:17

US3032337

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '25 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:05:17
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 17:12:57

US3032337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 17:12:57

US3032337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 17:12:57
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 17:12:57

US3032337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '25 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 17:12:57
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '12:08'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 17:12:57

US3032337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '25 Aug 2020 12:08'	System	25 Aug 2020 17:12:57

US3032337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 17:12:57

US3032337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'ONCE'	System	25 Aug 2020 17:12:57

US3032337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 17:12:57

US3032337

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:21:34
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '25 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:21:34
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	25 Aug 2020 18:21:36
User entered '11:37' reason for change: Data Entry Error	System	25 Aug 2020 18:21:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Kelsey Kelley (b) (4)	25 Aug 2020 18:21:34
User entered '11:7' (non-conformant).	(b) (4)	25 Aug 2020 18:21:34

US3032337

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '25 Aug 2020 11:37'	System	25 Aug 2020 18:21:36
User entered '25 Aug 2020 11:7' (non-conformant).	System	25 Aug 2020 18:21:34

US3032337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:55:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '25 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:21:50
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:21:50

US3032337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:21:50

US3032337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '11:32'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:21:50
	(b) (4)	

US3032337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '25 Aug 2020 11:32'	System	25 Aug 2020 18:21:50

US3032337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:21:50

US3032337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:21:50

US3032337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:21:50

US3032337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered empty.	System	25 Aug 2020 18:21:50

US3032337

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:21:56

US3032337

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '1'	System	25 Aug 2020 18:21:56

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:41:51', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '9609c2db-fab1-42e4-aa91-a107b90f3ab5' User entered 'Yes (Y)'	System	25 Aug 2020 17:42:11
	System	25 Aug 2020 17:42:11

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:41:58', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '9609c2db-fab1-42e4-aa91-a107b90f3ab5' User entered '98.6'	System	25 Aug 2020 17:42:11
	System	25 Aug 2020 17:42:11

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:42:05', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '9609c2db-fab1-42e4-aa91-a107b90f3ab5' User entered 'No (N)'	System	25 Aug 2020 17:42:11
	System	25 Aug 2020 17:42:11

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:42:10', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '9609c2db-fab1-42e4-aa91-a107b90f3ab5' User entered '25 Aug 2020 12:42'	System	25 Aug 2020 17:42:11
	System	25 Aug 2020 17:42:11

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '25 Aug 2020 12:28'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '25 Aug 2020 14:58'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:23:15', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'd1fe3509-2475-481c-beb3-14ded2948815' User entered 'Yes (Y)'	System	26 Aug 2020 04:23:33
	System	26 Aug 2020 04:23:33

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:23:19', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'd1fe3509-2475-481c-beb3-14ded2948815' User entered '99.4'	System	26 Aug 2020 04:23:33
	System	26 Aug 2020 04:23:33

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:23:22', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'd1fe3509-2475-481c-beb3-14ded2948815' User entered 'No (N)'	System	26 Aug 2020 04:23:33
	System	26 Aug 2020 04:23:33

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:23:28', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'd1fe3509-2475-481c-beb3-14ded2948815' User entered '25 Aug 2020 23:23'	System	26 Aug 2020 04:23:33
	System	26 Aug 2020 04:23:33

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '25 Aug 2020 15:53'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 2'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:10:55', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f17ac73f-a1cc-4a59-be8b-829d849549bf' User entered 'Yes (Y)'	System	27 Aug 2020 04:11:09
	System	27 Aug 2020 04:11:09

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:01', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f17ac73f-a1cc-4a59-be8b-829d849549bf' User entered '98.6'	System	27 Aug 2020 04:11:09
	System	27 Aug 2020 04:11:09

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:04', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f17ac73f-a1cc-4a59-be8b-829d849549bf' User entered 'No (N)'	System	27 Aug 2020 04:11:09
	System	27 Aug 2020 04:11:09

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f17ac73f-a1cc-4a59-be8b-829d849549bf' User entered '26 Aug 2020 23:11'	System	27 Aug 2020 04:11:09
	System	27 Aug 2020 04:11:09

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 3'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:02:41', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '0fa2edec-c80c-418a-a8cb-b2f009a06918' User entered 'Yes (Y)'	System	28 Aug 2020 04:02:52
	System	28 Aug 2020 04:02:52

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:02:46', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '0fa2edec-c80c-418a-a8cb-b2f009a06918' User entered '97.9'	System	28 Aug 2020 04:02:52
	System	28 Aug 2020 04:02:52

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:02:48', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '0fa2edec-c80c-418a-a8cb-b2f009a06918'	System	28 Aug 2020 04:02:52
User entered 'No (N)'	System	28 Aug 2020 04:02:52

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:02:50', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '0fa2edec-c80c-418a-a8cb-b2f009a06918' User entered '27 Aug 2020 23:02'	System	28 Aug 2020 04:02:52
	System	28 Aug 2020 04:02:52

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 4'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:08:51', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '71c02378-82e7-47ef-9e33-552f67ed87e6'	System	29 Aug 2020 15:09:07
User entered 'Yes (Y)'	System	29 Aug 2020 15:09:07

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:08:58', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '71c02378-82e7-47ef-9e33-552f67ed87e6' User entered '98.2'	System	29 Aug 2020 15:09:07
	System	29 Aug 2020 15:09:07

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:01', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '71c02378-82e7-47ef-9e33-552f67ed87e6'	System	29 Aug 2020 15:09:07
User entered 'No (N)'	System	29 Aug 2020 15:09:07

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:03', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '71c02378-82e7-47ef-9e33-552f67ed87e6' User entered '29 Aug 2020 10:09'	System	29 Aug 2020 15:09:07
	System	29 Aug 2020 15:09:07

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 5'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:36:50', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '3333b663-5934-416b-a013-81bf5eeac9ae' User entered 'Yes (Y)'	System	30 Aug 2020 14:37:08
	System	30 Aug 2020 14:37:08

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '3333b663-5934-416b-a013-81bf5eac9ae' User entered '96.7'	System	30 Aug 2020 14:37:08
	System	30 Aug 2020 14:37:08

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:03', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '3333b663-5934-416b-a013-81bf5eeac9ae' User entered 'No (N)'	System	30 Aug 2020 14:37:08
	System	30 Aug 2020 14:37:08

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:05', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '3333b663-5934-416b-a013-81bf5eeac9ae' User entered '30 Aug 2020 09:37'	System	30 Aug 2020 14:37:08
	System	30 Aug 2020 14:37:08

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 6'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 7'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:53:51', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f8a46956-e389-4cc1-8b17-22bc2a1d64ff' User entered 'Yes (Y)'	System	31 Aug 2020 23:54:08
	System	31 Aug 2020 23:54:08

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:03', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f8a46956-e389-4cc1-8b17-22bc2a1d64ff' User entered '98.3'	System	31 Aug 2020 23:54:08
	System	31 Aug 2020 23:54:08

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:05', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f8a46956-e389-4cc1-8b17-22bc2a1d64ff'	System	31 Aug 2020 23:54:08
User entered 'No (N)'	System	31 Aug 2020 23:54:08

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:07', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f8a46956-e389-4cc1-8b17-22bc2a1d64ff' User entered '31 Aug 2020 18:54'	System	31 Aug 2020 23:54:08
	System	31 Aug 2020 23:54:08

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:42:18', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '38906ea0-9d51-4cde-902e-afc518c6d868'	System	25 Aug 2020 17:42:40
User entered 'None (1)'	System	25 Aug 2020 17:42:40

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:42:26', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '38906ea0-9d51-4cde-902e-afc518c6d868' User entered 'No (N)'	System	25 Aug 2020 17:42:40
	System	25 Aug 2020 17:42:40

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:42:29', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '38906ea0-9d51-4cde-902e-afc518c6d868' User entered 'No (N)'	System	25 Aug 2020 17:42:40
	System	25 Aug 2020 17:42:40

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:42:34', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '38906ea0-9d51-4cde-902e-afc518c6d868' User entered 'None (1)'	System	25 Aug 2020 17:42:40
	System	25 Aug 2020 17:42:40

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:42:36', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '38906ea0-9d51-4cde-902e-afc518c6d868' User entered '25 Aug 2020 12:42'	System	25 Aug 2020 17:42:40
	System	25 Aug 2020 17:42:40

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '25 Aug 2020 12:28'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '25 Aug 2020 14:58'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:23:43', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '98de4f98-45e5-4bf0-888d-4036a08ea2aa'	System	26 Aug 2020 04:24:21
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 04:24:21

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:23:47', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '98de4f98-45e5-4bf0-888d-4036a08ea2aa' User entered 'No (N)'	System	26 Aug 2020 04:24:21
	System	26 Aug 2020 04:24:21

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:24:01', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '98de4f98-45e5-4bf0-888d-4036a08ea2aa' User entered 'No (N)'	System	26 Aug 2020 04:24:21
	System	26 Aug 2020 04:24:21

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:24:11', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '98de4f98-45e5-4bf0-888d-4036a08ea2aa'	System	26 Aug 2020 04:24:21
User entered 'None (1)'	System	26 Aug 2020 04:24:21

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:24:19', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '98de4f98-45e5-4bf0-888d-4036a08ea2aa' User entered '25 Aug 2020 23:24'	System	26 Aug 2020 04:24:21
	System	26 Aug 2020 04:24:21

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '25 Aug 2020 15:53'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 2'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:13', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a368dd94-bf66-4a42-8cd8-b191edea2eb3'	System	27 Aug 2020 04:11:34
User entered 'None (1)'	System	27 Aug 2020 04:11:34

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:21', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a368dd94-bf66-4a42-8cd8-b191edea2eb3'	System	27 Aug 2020 04:11:34
User entered 'No (N)'	System	27 Aug 2020 04:11:34

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:23', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a368dd94-bf66-4a42-8cd8-b191edea2eb3'	System	27 Aug 2020 04:11:34
User entered 'No (N)'	System	27 Aug 2020 04:11:34

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:27', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a368dd94-bf66-4a42-8cd8-b191edea2eb3'	System	27 Aug 2020 04:11:34
User entered 'None (1)'	System	27 Aug 2020 04:11:34

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:31', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a368dd94-bf66-4a42-8cd8-b191edea2eb3' User entered '26 Aug 2020 23:11'	System	27 Aug 2020 04:11:34
	System	27 Aug 2020 04:11:34

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 3'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:02:53', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f542b689-7b5b-4298-b8a6-b6e78d3f3ed5'	System	28 Aug 2020 04:03:04
User entered 'None (1)'	System	28 Aug 2020 04:03:04

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:02:55', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f542b689-7b5b-4298-b8a6-b6e78d3f3ed5'	System	28 Aug 2020 04:03:04
User entered 'No (N)'	System	28 Aug 2020 04:03:04

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:02:56', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f542b689-7b5b-4298-b8a6-b6e78d3f3ed5'	System	28 Aug 2020 04:03:04
User entered 'No (N)'	System	28 Aug 2020 04:03:04

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:02:57', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f542b689-7b5b-4298-b8a6-b6e78d3f3ed5'	System	28 Aug 2020 04:03:04
User entered 'None (1)'	System	28 Aug 2020 04:03:04

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:02:59', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f542b689-7b5b-4298-b8a6-b6e78d3f3ed5' User entered '27 Aug 2020 23:02'	System	28 Aug 2020 04:03:04
	System	28 Aug 2020 04:03:04

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 4'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2654fcd0-fd76-4546-a99e-23062a663fe6'	System	29 Aug 2020 15:09:18
User entered 'None (1)'	System	29 Aug 2020 15:09:18

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:08', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2654fcd0-fd76-4546-a99e-23062a663fe6'	System	29 Aug 2020 15:09:18
User entered 'No (N)'	System	29 Aug 2020 15:09:18

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:09', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2654fcd0-fd76-4546-a99e-23062a663fe6' User entered 'No (N)'	System	29 Aug 2020 15:09:18
	System	29 Aug 2020 15:09:18

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:11', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2654fcd0-fd76-4546-a99e-23062a663fe6'	System	29 Aug 2020 15:09:18
User entered 'None (1)'	System	29 Aug 2020 15:09:18

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:12', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2654fcd0-fd76-4546-a99e-23062a663fe6' User entered '29 Aug 2020 10:09'	System	29 Aug 2020 15:09:18
	System	29 Aug 2020 15:09:18

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 5'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:08', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '65a1e238-86df-402e-a180-4f02bce65123'	System	30 Aug 2020 14:37:19
User entered 'None (1)'	System	30 Aug 2020 14:37:19

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:09', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '65a1e238-86df-402e-a180-4f02bce65123' User entered 'No (N)'	System	30 Aug 2020 14:37:19
	System	30 Aug 2020 14:37:19

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:11', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '65a1e238-86df-402e-a180-4f02bce65123' User entered 'No (N)'	System	30 Aug 2020 14:37:19
	System	30 Aug 2020 14:37:19

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:12', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '65a1e238-86df-402e-a180-4f02bce65123'	System	30 Aug 2020 14:37:19
User entered 'None (1)'	System	30 Aug 2020 14:37:19

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:13', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '65a1e238-86df-402e-a180-4f02bce65123' User entered '30 Aug 2020 09:37'	System	30 Aug 2020 14:37:19
	System	30 Aug 2020 14:37:19

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 6'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 7'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:09', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '594eb712-6a5b-4676-97b4-01e984165856'	System	31 Aug 2020 23:54:21
User entered 'None (1)'	System	31 Aug 2020 23:54:21

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:10', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '594eb712-6a5b-4676-97b4-01e984165856'	System	31 Aug 2020 23:54:21
User entered 'No (N)'	System	31 Aug 2020 23:54:21

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:11', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '594eb712-6a5b-4676-97b4-01e984165856'	System	31 Aug 2020 23:54:21
User entered 'No (N)'	System	31 Aug 2020 23:54:21

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:12', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '594eb712-6a5b-4676-97b4-01e984165856'	System	31 Aug 2020 23:54:21
User entered 'None (1)'	System	31 Aug 2020 23:54:21

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:14', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '594eb712-6a5b-4676-97b4-01e984165856' User entered '31 Aug 2020 18:54'	System	31 Aug 2020 23:54:21
	System	31 Aug 2020 23:54:21

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:42:43', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b36b4676-db41-498e-9739-ab52ce28983d' User entered 'None (0)'	System	25 Aug 2020 17:43:04
	System	25 Aug 2020 17:43:04

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:42:45', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b36b4676-db41-498e-9739-ab52ce28983d' User entered 'None (0)'	System	25 Aug 2020 17:43:04
	System	25 Aug 2020 17:43:04

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:42:48', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b36b4676-db41-498e-9739-ab52ce28983d' User entered 'None (0)'	System	25 Aug 2020 17:43:04
	System	25 Aug 2020 17:43:04

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:42:50', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b36b4676-db41-498e-9739-ab52ce28983d' User entered 'None (0)'	System	25 Aug 2020 17:43:04
	System	25 Aug 2020 17:43:04

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:42:51', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b36b4676-db41-498e-9739-ab52ce28983d' User entered 'None (0)'	System	25 Aug 2020 17:43:04
	System	25 Aug 2020 17:43:04

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:42:53', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b36b4676-db41-498e-9739-ab52ce28983d' User entered 'None (0)'	System	25 Aug 2020 17:43:04
	System	25 Aug 2020 17:43:04

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:43:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b36b4676-db41-498e-9739-ab52ce28983d'	System	25 Aug 2020 17:43:04
User entered 'No (N)'	System	25 Aug 2020 17:43:04

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T12:43:02', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b36b4676-db41-498e-9739-ab52ce28983d' User entered '25 Aug 2020 12:43'	System	25 Aug 2020 17:43:04
	System	25 Aug 2020 17:43:04

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '25 Aug 2020 12:28'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '25 Aug 2020 14:58'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:24:23', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '98051d1d-641e-411c-9e67-688a8fa9d120' User entered 'None (0)'	System	26 Aug 2020 04:24:56
	System	26 Aug 2020 04:24:56

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:24:36', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '98051d1d-641e-411c-9e67-688a8fa9d120' User entered 'Some interference with activity (2)'	System	26 Aug 2020 04:24:56
	System	26 Aug 2020 04:24:56

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:24:41', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '98051d1d-641e-411c-9e67-688a8fa9d120'	System	26 Aug 2020 04:24:56
User entered 'No interference with activity (1)'	System	26 Aug 2020 04:24:56

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:24:44', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '98051d1d-641e-411c-9e67-688a8fa9d120'	System	26 Aug 2020 04:24:56
User entered 'No interference with activity (1)'	System	26 Aug 2020 04:24:56

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:24:46', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '98051d1d-641e-411c-9e67-688a8fa9d120' User entered 'None (0)'	System	26 Aug 2020 04:24:56
	System	26 Aug 2020 04:24:56

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:24:48', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '98051d1d-641e-411c-9e67-688a8fa9d120' User entered 'None (0)'	System	26 Aug 2020 04:24:56
	System	26 Aug 2020 04:24:56

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:24:51', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '98051d1d-641e-411c-9e67-688a8fa9d120' User entered 'No (N)'	System	26 Aug 2020 04:24:56
	System	26 Aug 2020 04:24:56

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-25T23:24:53', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '98051d1d-641e-411c-9e67-688a8fa9d120' User entered '25 Aug 2020 23:24'	System	26 Aug 2020 04:24:56
	System	26 Aug 2020 04:24:56

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '25 Aug 2020 15:53'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 2'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:35', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '93e32d91-0a8b-48d4-91cc-2347e79573ca' User entered 'None (0)'	System	27 Aug 2020 04:11:51
	System	27 Aug 2020 04:11:51

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:38', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '93e32d91-0a8b-48d4-91cc-2347e79573ca' User entered 'None (0)'	System	27 Aug 2020 04:11:51
	System	27 Aug 2020 04:11:51

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:39', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '93e32d91-0a8b-48d4-91cc-2347e79573ca' User entered 'None (0)'	System	27 Aug 2020 04:11:51
	System	27 Aug 2020 04:11:51

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:41', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '93e32d91-0a8b-48d4-91cc-2347e79573ca' User entered 'None (0)'	System	27 Aug 2020 04:11:51
	System	27 Aug 2020 04:11:51

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:42', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '93e32d91-0a8b-48d4-91cc-2347e79573ca' User entered 'None (0)'	System	27 Aug 2020 04:11:51
	System	27 Aug 2020 04:11:51

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:44', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '93e32d91-0a8b-48d4-91cc-2347e79573ca' User entered 'None (0)'	System	27 Aug 2020 04:11:51
	System	27 Aug 2020 04:11:51

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:46', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '93e32d91-0a8b-48d4-91cc-2347e79573ca' User entered 'No (N)'	System	27 Aug 2020 04:11:51
	System	27 Aug 2020 04:11:51

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-26T23:11:47', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '93e32d91-0a8b-48d4-91cc-2347e79573ca' User entered '26 Aug 2020 23:11'	System	27 Aug 2020 04:11:51
	System	27 Aug 2020 04:11:51

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 3'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:03:02', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'c85cb666-92e4-4f9f-9f92-23c8e63db40b' User entered 'None (0)'	System	28 Aug 2020 04:03:15
	System	28 Aug 2020 04:03:15

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:03:03', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'c85cb666-92e4-4f9f-9f92-23c8e63db40b' User entered 'None (0)'	System	28 Aug 2020 04:03:15
	System	28 Aug 2020 04:03:15

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:03:04', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'c85cb666-92e4-4f9f-9f92-23c8e63db40b' User entered 'None (0)'	System	28 Aug 2020 04:03:15
	System	28 Aug 2020 04:03:15

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:03:05', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'c85cb666-92e4-4f9f-9f92-23c8e63db40b' User entered 'None (0)'	System	28 Aug 2020 04:03:15
	System	28 Aug 2020 04:03:15

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:03:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'c85cb666-92e4-4f9f-9f92-23c8e63db40b' User entered 'None (0)'	System	28 Aug 2020 04:03:15
	System	28 Aug 2020 04:03:15

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:03:07', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'c85cb666-92e4-4f9f-9f92-23c8e63db40b' User entered 'None (0)'	System	28 Aug 2020 04:03:15
	System	28 Aug 2020 04:03:15

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:03:09', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'c85cb666-92e4-4f9f-9f92-23c8e63db40b' User entered 'No (N)'	System	28 Aug 2020 04:03:15
	System	28 Aug 2020 04:03:15

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-27T23:03:11', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'c85cb666-92e4-4f9f-9f92-23c8e63db40b' User entered '27 Aug 2020 23:03'	System	28 Aug 2020 04:03:15
	System	28 Aug 2020 04:03:15

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 4'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:15', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'e5eeeb21-8162-493f-b958-9a67a2eb1429' User entered 'None (0)'	System	29 Aug 2020 15:09:28
	System	29 Aug 2020 15:09:28

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:16', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'e5eeeb21-8162-493f-b958-9a67a2eb1429' User entered 'None (0)'	System	29 Aug 2020 15:09:28
	System	29 Aug 2020 15:09:28

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:17', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'e5eeeb21-8162-493f-b958-9a67a2eb1429' User entered 'None (0)'	System	29 Aug 2020 15:09:28
	System	29 Aug 2020 15:09:28

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:18', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'e5eeeb21-8162-493f-b958-9a67a2eb1429' User entered 'None (0)'	System	29 Aug 2020 15:09:28
	System	29 Aug 2020 15:09:28

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:19', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'e5eeeb21-8162-493f-b958-9a67a2eb1429' User entered 'None (0)'	System	29 Aug 2020 15:09:28
	System	29 Aug 2020 15:09:28

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:21', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'e5eeeb21-8162-493f-b958-9a67a2eb1429' User entered 'None (0)'	System	29 Aug 2020 15:09:28
	System	29 Aug 2020 15:09:28

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:23', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'e5eeeb21-8162-493f-b958-9a67a2eb1429' User entered 'No (N)'	System	29 Aug 2020 15:09:28
	System	29 Aug 2020 15:09:28

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-29T10:09:25', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'e5eeeb21-8162-493f-b958-9a67a2eb1429' User entered '29 Aug 2020 10:09'	System	29 Aug 2020 15:09:28
	System	29 Aug 2020 15:09:28

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 5'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:17', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'de91be9f-36af-4b50-9a87-e2ec44aa3e87' User entered 'None (0)'	System	30 Aug 2020 14:37:30
	System	30 Aug 2020 14:37:30

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:19', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'de91be9f-36af-4b50-9a87-e2ec44aa3e87' User entered 'None (0)'	System	30 Aug 2020 14:37:30
	System	30 Aug 2020 14:37:30

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:20', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'de91be9f-36af-4b50-9a87-e2ec44aa3e87'	System	30 Aug 2020 14:37:30
User entered 'None (0)'	System	30 Aug 2020 14:37:30

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:21', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'de91be9f-36af-4b50-9a87-e2ec44aa3e87'	System	30 Aug 2020 14:37:30
User entered 'None (0)'	System	30 Aug 2020 14:37:30

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:22', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'de91be9f-36af-4b50-9a87-e2ec44aa3e87'	System	30 Aug 2020 14:37:30
User entered 'None (0)'	System	30 Aug 2020 14:37:30

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:23', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'de91be9f-36af-4b50-9a87-e2ec44aa3e87'	System	30 Aug 2020 14:37:30
User entered 'None (0)'	System	30 Aug 2020 14:37:30

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:24', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'de91be9f-36af-4b50-9a87-e2ec44aa3e87' User entered 'No (N)'	System	30 Aug 2020 14:37:30
	System	30 Aug 2020 14:37:30

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-30T09:37:26', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'de91be9f-36af-4b50-9a87-e2ec44aa3e87' User entered '30 Aug 2020 09:37'	System	30 Aug 2020 14:37:30
	System	30 Aug 2020 14:37:30

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 6'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 7'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:17', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '07bb4018-6e84-45ca-a47f-96189542d9f9' User entered 'None (0)'	System	31 Aug 2020 23:54:27
	System	31 Aug 2020 23:54:27

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:18', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '07bb4018-6e84-45ca-a47f-96189542d9f9' User entered 'None (0)'	System	31 Aug 2020 23:54:27
	System	31 Aug 2020 23:54:27

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:19', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '07bb4018-6e84-45ca-a47f-96189542d9f9' User entered 'None (0)'	System	31 Aug 2020 23:54:27
	System	31 Aug 2020 23:54:27

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:20', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '07bb4018-6e84-45ca-a47f-96189542d9f9' User entered 'None (0)'	System	31 Aug 2020 23:54:27
	System	31 Aug 2020 23:54:27

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:21', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '07bb4018-6e84-45ca-a47f-96189542d9f9' User entered 'None (0)'	System	31 Aug 2020 23:54:27
	System	31 Aug 2020 23:54:27

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:21', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '07bb4018-6e84-45ca-a47f-96189542d9f9' User entered 'None (0)'	System	31 Aug 2020 23:54:27
	System	31 Aug 2020 23:54:27

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:23', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '07bb4018-6e84-45ca-a47f-96189542d9f9' User entered 'No (N)'	System	31 Aug 2020 23:54:27
	System	31 Aug 2020 23:54:27

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-08-31T18:54:24', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '07bb4018-6e84-45ca-a47f-96189542d9f9' User entered '31 Aug 2020 18:54'	System	31 Aug 2020 23:54:27
	System	31 Aug 2020 23:54:27

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 17:12:57

US3032337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:03

US3032337

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:03

US3032337

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:03

US3032337

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:03

US3032337

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:07

US3032337

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '1'	System	10 Sep 2020 17:22:07

US3032337

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:26

US3032337

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:26

US3032337

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:26

US3032337

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:26

US3032337

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:30

US3032337

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '1'	System	10 Sep 2020 17:22:30

US3032337

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:46:42

US3032337

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:46:42

US3032337

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:46:42

US3032337

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:46:42

US3032337

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:48:50

US3032337

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '1'	System	15 Sep 2020 14:48:50

US3032337

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:53:37

US3032337

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '22 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:53:37
	(b) (4)	

US3032337

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:53:37

US3032337

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'VISIT2'	System	22 Sep 2020 18:53:37

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '22 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:48:33
	(b) (4)	

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '12:22'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:48:33
	(b) (4)	

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '22 Sep 2020 12:22'	System	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '36.9' C	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '79'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'bpm'	System	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'breaths/min'	System	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '126'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'mmHg'	System	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '81'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'mmHg'	System	22 Sep 2020 19:48:33

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 19:50:26

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:50:26
	(b) (4)	

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '22 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:50:26
	(b) (4)	

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '14:06'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:50:26

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '22 Sep 2020 14:06'	System	22 Sep 2020 19:50:26

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '36.8' C	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:50:26

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:50:26
	(b) (4)	

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:50:26

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '84'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:50:26

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'bpm'	System	22 Sep 2020 19:50:26

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:50:26

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'breaths/min'	System	22 Sep 2020 19:50:26

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '123'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:50:26
	(b) (4)	

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'mmHg'	System	22 Sep 2020 19:50:26

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '78'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 19:50:26

US3032337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'mmHg'	System	22 Sep 2020 19:50:26

US3032337

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:34

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:53:44

US3032337

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '22 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:53:44

US3032337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:03

US3032337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:03

US3032337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	Linden DeBoer (b) (4)	22 Sep 2020 18:54:03

US3032337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 18:54:03

US3032337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '22 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:03
	(b) (4)	

US3032337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '13:36'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:03

US3032337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '22 Sep 2020 13:36'	System	22 Sep 2020 18:54:03

US3032337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:03

US3032337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'ONCE'	System	22 Sep 2020 18:54:03

US3032337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 18:54:03

US3032337

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:14

US3032337

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '22 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:14
	(b) (4)	

US3032337

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '12:48'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:14

US3032337

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '22 Sep 2020 12:48'	System	22 Sep 2020 18:54:14

US3032337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:55:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '22 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:27
	(b) (4)	

US3032337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 18:54:27

US3032337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:27

US3032337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered '12:37'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:27

US3032337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '22 Sep 2020 12:37'	System	22 Sep 2020 18:54:27

US3032337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 18:54:27

US3032337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:27

US3032337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered empty.	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:27

US3032337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered empty.	System	22 Sep 2020 18:54:27

US3032337

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 18:54:30

US3032337

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '1'	System	22 Sep 2020 18:54:30

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:06:45', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '08bfb5ae-f0ae-4ba7-a392-30929fc17b4d' User entered 'Yes (Y)'	System	22 Sep 2020 19:06:56
	System	22 Sep 2020 19:06:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:06:49', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '08bfb5ae-f0ae-4ba7-a392-30929fc17b4d' User entered '98.3'	System	22 Sep 2020 19:06:56
	System	22 Sep 2020 19:06:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:06:51', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '08bfb5ae-f0ae-4ba7-a392-30929fc17b4d'	System	22 Sep 2020 19:06:56
User entered 'No (N)'	System	22 Sep 2020 19:06:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:06:53', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '08bfb5ae-f0ae-4ba7-a392-30929fc17b4d' User entered '22 Sep 2020 14:06'	System	22 Sep 2020 19:06:56
	System	22 Sep 2020 19:06:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '22 Sep 2020 13:56'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '22 Sep 2020 16:26'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:02', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '8df43178-c30b-4485-84d0-642119571fb9' User entered 'Yes (Y)'	System	23 Sep 2020 04:32:18
	System	23 Sep 2020 04:32:18

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:08', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '8df43178-c30b-4485-84d0-642119571fb9' User entered '101.6'	System	23 Sep 2020 04:32:18
	System	23 Sep 2020 04:32:18

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:12', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '8df43178-c30b-4485-84d0-642119571fb9' User entered 'No (N)'	System	23 Sep 2020 04:32:18
	System	23 Sep 2020 04:32:18

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:14', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '8df43178-c30b-4485-84d0-642119571fb9' User entered '22 Sep 2020 23:32'	System	23 Sep 2020 04:32:18
	System	23 Sep 2020 04:32:18

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '22 Sep 2020 17:21'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 2'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:35:46', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2eb99741-55d9-49b3-8fb9-3a32288feef6' User entered 'Yes (Y)'	System	24 Sep 2020 05:35:55
	System	24 Sep 2020 05:35:55

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:35:49', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2eb99741-55d9-49b3-8fb9-3a32288feef6' User entered '101.6'	System	24 Sep 2020 05:35:55
	System	24 Sep 2020 05:35:55

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:35:51', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2eb99741-55d9-49b3-8fb9-3a32288feef6'	System	24 Sep 2020 05:35:55
User entered 'No (N)'	System	24 Sep 2020 05:35:55

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:35:53', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2eb99741-55d9-49b3-8fb9-3a32288feef6' User entered '24 Sep 2020 00:35'	System	24 Sep 2020 05:35:55
	System	24 Sep 2020 05:35:55

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 3'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:51:40', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'ab8194e0-8ff5-40de-ae8c-616de82a6f44' User entered 'Yes (Y)'	System	24 Sep 2020 18:51:56
	System	24 Sep 2020 18:51:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:51:45', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'ab8194e0-8ff5-40de-ae8c-616de82a6f44' User entered '100.3'	System	24 Sep 2020 18:51:56
	System	24 Sep 2020 18:51:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:51:47', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'ab8194e0-8ff5-40de-ae8c-616de82a6f44'	System	24 Sep 2020 18:51:56
User entered 'No (N)'	System	24 Sep 2020 18:51:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:51:49', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'ab8194e0-8ff5-40de-ae8c-616de82a6f44' User entered '24 Sep 2020 13:51'	System	24 Sep 2020 18:51:56
	System	24 Sep 2020 18:51:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 4'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 5'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:01:02', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edf28a3e-23d8-49fb-95fc-c7a9fcae98d1' User entered 'Yes (Y)'	System	27 Sep 2020 15:01:19
	System	27 Sep 2020 15:01:19

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:01:09', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edf28a3e-23d8-49fb-95fc-c7a9fcae98d1' User entered '97.5'	System	27 Sep 2020 15:01:19
	System	27 Sep 2020 15:01:19

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:01:14', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edf28a3e-23d8-49fb-95fc-c7a9fcae98d1'	System	27 Sep 2020 15:01:19
User entered 'No (N)'	System	27 Sep 2020 15:01:19

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:01:16', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edf28a3e-23d8-49fb-95fc-c7a9fcae98d1' User entered '27 Sep 2020 10:01'	System	27 Sep 2020 15:01:19
	System	27 Sep 2020 15:01:19

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 6'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 7'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:10:49', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '43d966a1-e076-4910-9530-f273797cabe3' User entered 'Yes (Y)'	System	29 Sep 2020 11:11:06
	System	29 Sep 2020 11:11:06

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:10:59', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '43d966a1-e076-4910-9530-f273797cabe3' User entered '98.3'	System	29 Sep 2020 11:11:06
	System	29 Sep 2020 11:11:06

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:01', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '43d966a1-e076-4910-9530-f273797cabe3' User entered 'No (N)'	System	29 Sep 2020 11:11:06
	System	29 Sep 2020 11:11:06

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:03', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '43d966a1-e076-4910-9530-f273797cabe3' User entered '29 Sep 2020 06:11'	System	29 Sep 2020 11:11:06
	System	29 Sep 2020 11:11:06

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:06:57', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'c7eb85fc-eb14-4a46-81ac-f06a93e5152c'	System	22 Sep 2020 19:07:49
User entered 'None (1)'	System	22 Sep 2020 19:07:49

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:07:42', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'c7eb85fc-eb14-4a46-81ac-f06a93e5152c' User entered 'No (N)'	System	22 Sep 2020 19:07:49
	System	22 Sep 2020 19:07:49

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:07:43', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'c7eb85fc-eb14-4a46-81ac-f06a93e5152c'	System	22 Sep 2020 19:07:49
User entered 'No (N)'	System	22 Sep 2020 19:07:49

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:07:44', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'c7eb85fc-eb14-4a46-81ac-f06a93e5152c'	System	22 Sep 2020 19:07:49
User entered 'None (1)'	System	22 Sep 2020 19:07:49

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:07:46', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'c7eb85fc-eb14-4a46-81ac-f06a93e5152c' User entered '22 Sep 2020 14:07'	System	22 Sep 2020 19:07:49
	System	22 Sep 2020 19:07:49

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '22 Sep 2020 13:56'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '22 Sep 2020 16:26'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:40', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '55e2a7d2-7d63-4a82-8356-fff193fb31af'	System	23 Sep 2020 04:32:45
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	23 Sep 2020 04:32:45

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:19', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '55e2a7d2-7d63-4a82-8356-fff193fb31af' User entered 'No (N)'	System	23 Sep 2020 04:32:45
	System	23 Sep 2020 04:32:45

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:20', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '55e2a7d2-7d63-4a82-8356-fff193fb31af'	System	23 Sep 2020 04:32:45
User entered 'No (N)'	System	23 Sep 2020 04:32:45

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:21', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '55e2a7d2-7d63-4a82-8356-fff193fb31af' User entered 'None (1)'	System	23 Sep 2020 04:32:45
	System	23 Sep 2020 04:32:45

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:41', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '55e2a7d2-7d63-4a82-8356-fff193fb31af' User entered '22 Sep 2020 23:32'	System	23 Sep 2020 04:32:45
	System	23 Sep 2020 04:32:45

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '22 Sep 2020 17:21'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 2'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:35:56', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'da4e1afc-a662-4c14-9b7f-5a40ae321936'	System	24 Sep 2020 05:36:06
User entered 'None (1)'	System	24 Sep 2020 05:36:06

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:35:58', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'da4e1afc-a662-4c14-9b7f-5a40ae321936'	System	24 Sep 2020 05:36:06
User entered 'No (N)'	System	24 Sep 2020 05:36:06

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:35:59', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'da4e1afc-a662-4c14-9b7f-5a40ae321936'	System	24 Sep 2020 05:36:06
User entered 'No (N)'	System	24 Sep 2020 05:36:06

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:36:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'da4e1afc-a662-4c14-9b7f-5a40ae321936'	System	24 Sep 2020 05:36:06
User entered 'None (1)'	System	24 Sep 2020 05:36:06

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:36:02', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'da4e1afc-a662-4c14-9b7f-5a40ae321936' User entered '24 Sep 2020 00:36'	System	24 Sep 2020 05:36:06
	System	24 Sep 2020 05:36:06

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 3'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:51:52', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '22ce7a9b-7ff0-4dd3-bc9d-87fc89145e9a' User entered 'None (1)'	System	24 Sep 2020 18:52:00
	System	24 Sep 2020 18:52:00

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:51:53', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '22ce7a9b-7ff0-4dd3-bc9d-87fc89145e9a' User entered 'No (N)'	System	24 Sep 2020 18:52:00
	System	24 Sep 2020 18:52:00

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:51:54', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '22ce7a9b-7ff0-4dd3-bc9d-87fc89145e9a' User entered 'No (N)'	System	24 Sep 2020 18:52:00
	System	24 Sep 2020 18:52:00

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:51:56', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '22ce7a9b-7ff0-4dd3-bc9d-87fc89145e9a'	System	24 Sep 2020 18:52:00
User entered 'None (1)'	System	24 Sep 2020 18:52:00

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:51:57', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '22ce7a9b-7ff0-4dd3-bc9d-87fc89145e9a' User entered '24 Sep 2020 13:51'	System	24 Sep 2020 18:52:00
	System	24 Sep 2020 18:52:00

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 4'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 5'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:02:25', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '04df176e-6d78-4c7e-a1e0-4f8d6f9f43da'	System	27 Sep 2020 15:02:37
User entered 'None (1)'	System	27 Sep 2020 15:02:37

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:02:27', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '04df176e-6d78-4c7e-a1e0-4f8d6f9f43da' User entered 'No (N)'	System	27 Sep 2020 15:02:37
	System	27 Sep 2020 15:02:37

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:02:29', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '04df176e-6d78-4c7e-a1e0-4f8d6f9f43da' User entered 'No (N)'	System	27 Sep 2020 15:02:37
	System	27 Sep 2020 15:02:37

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:02:30', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '04df176e-6d78-4c7e-a1e0-4f8d6f9f43da'	System	27 Sep 2020 15:02:37
User entered 'None (1)'	System	27 Sep 2020 15:02:37

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:02:32', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '04df176e-6d78-4c7e-a1e0-4f8d6f9f43da' User entered '27 Sep 2020 10:02'	System	27 Sep 2020 15:02:37
	System	27 Sep 2020 15:02:37

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 6'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 7'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '40c72257-4467-49c5-b9aa-caf3bdf4d6c1' User entered 'None (1)'	System	29 Sep 2020 11:11:14
	System	29 Sep 2020 11:11:14

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:08', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '40c72257-4467-49c5-b9aa-caf3bdf4d6c1'	System	29 Sep 2020 11:11:14
User entered 'No (N)'	System	29 Sep 2020 11:11:14

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:09', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '40c72257-4467-49c5-b9aa-caf3bdf4d6c1'	System	29 Sep 2020 11:11:14
User entered 'No (N)'	System	29 Sep 2020 11:11:14

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:10', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '40c72257-4467-49c5-b9aa-caf3bdf4d6c1'	System	29 Sep 2020 11:11:14
User entered 'None (1)'	System	29 Sep 2020 11:11:14

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:12', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '40c72257-4467-49c5-b9aa-caf3bdf4d6c1' User entered '29 Sep 2020 06:11'	System	29 Sep 2020 11:11:14
	System	29 Sep 2020 11:11:14

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:07:50', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a9805172-bac1-4d59-8635-99a2d59dd9fd' User entered 'None (0)'	System	22 Sep 2020 19:08:05
	System	22 Sep 2020 19:08:05

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:07:51', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a9805172-bac1-4d59-8635-99a2d59dd9fd' User entered 'None (0)'	System	22 Sep 2020 19:08:05
	System	22 Sep 2020 19:08:05

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:07:53', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a9805172-bac1-4d59-8635-99a2d59dd9fd' User entered 'None (0)'	System	22 Sep 2020 19:08:05
	System	22 Sep 2020 19:08:05

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:07:54', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a9805172-bac1-4d59-8635-99a2d59dd9fd' User entered 'None (0)'	System	22 Sep 2020 19:08:05
	System	22 Sep 2020 19:08:05

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:07:56', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a9805172-bac1-4d59-8635-99a2d59dd9fd' User entered 'None (0)'	System	22 Sep 2020 19:08:05
	System	22 Sep 2020 19:08:05

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:07:57', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a9805172-bac1-4d59-8635-99a2d59dd9fd' User entered 'None (0)'	System	22 Sep 2020 19:08:05
	System	22 Sep 2020 19:08:05

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:08:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a9805172-bac1-4d59-8635-99a2d59dd9fd' User entered 'No (N)'	System	22 Sep 2020 19:08:05
	System	22 Sep 2020 19:08:05

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T14:08:02', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a9805172-bac1-4d59-8635-99a2d59dd9fd' User entered '22 Sep 2020 14:08'	System	22 Sep 2020 19:08:05
	System	22 Sep 2020 19:08:05

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '22 Sep 2020 13:56'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '22 Sep 2020 16:26'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:44', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '56093988-141a-415f-9b01-5ba0da8279da' User entered 'None (0)'	System	23 Sep 2020 04:33:04
	System	23 Sep 2020 04:33:04

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:46', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '56093988-141a-415f-9b01-5ba0da8279da' User entered 'None (0)'	System	23 Sep 2020 04:33:04
	System	23 Sep 2020 04:33:04

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:48', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '56093988-141a-415f-9b01-5ba0da8279da' User entered 'No interference with activity (1)'	System	23 Sep 2020 04:33:04
	System	23 Sep 2020 04:33:04

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:50', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '56093988-141a-415f-9b01-5ba0da8279da' User entered 'None (0)'	System	23 Sep 2020 04:33:04
	System	23 Sep 2020 04:33:04

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:51', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '56093988-141a-415f-9b01-5ba0da8279da' User entered 'None (0)'	System	23 Sep 2020 04:33:04
	System	23 Sep 2020 04:33:04

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:55', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '56093988-141a-415f-9b01-5ba0da8279da'	System	23 Sep 2020 04:33:04
User entered 'Some interference with activity not requiring medical attention (2)'	System	23 Sep 2020 04:33:04

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:32:58', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '56093988-141a-415f-9b01-5ba0da8279da' User entered 'No (N)'	System	23 Sep 2020 04:33:04
	System	23 Sep 2020 04:33:04

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-22T23:33:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '56093988-141a-415f-9b01-5ba0da8279da' User entered '22 Sep 2020 23:33'	System	23 Sep 2020 04:33:04
	System	23 Sep 2020 04:33:04

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '22 Sep 2020 17:21'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 2'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:36:08', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '01e268cd-4ae7-4a15-a0c5-8a8e1d5af611'	System	24 Sep 2020 05:36:22
User entered 'No interference with activity (1)'	System	24 Sep 2020 05:36:22

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:36:10', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '01e268cd-4ae7-4a15-a0c5-8a8e1d5af611' User entered 'None (0)'	System	24 Sep 2020 05:36:22
	System	24 Sep 2020 05:36:22

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:36:12', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '01e268cd-4ae7-4a15-a0c5-8a8e1d5af611' User entered 'None (0)'	System	24 Sep 2020 05:36:22
	System	24 Sep 2020 05:36:22

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:36:13', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '01e268cd-4ae7-4a15-a0c5-8a8e1d5af611' User entered 'None (0)'	System	24 Sep 2020 05:36:22
	System	24 Sep 2020 05:36:22

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:36:14', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '01e268cd-4ae7-4a15-a0c5-8a8e1d5af611' User entered 'None (0)'	System	24 Sep 2020 05:36:22
	System	24 Sep 2020 05:36:22

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:36:15', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '01e268cd-4ae7-4a15-a0c5-8a8e1d5af611' User entered 'None (0)'	System	24 Sep 2020 05:36:22
	System	24 Sep 2020 05:36:22

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:36:17', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '01e268cd-4ae7-4a15-a0c5-8a8e1d5af611' User entered 'No (N)'	System	24 Sep 2020 05:36:22
	System	24 Sep 2020 05:36:22

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T00:36:19', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '01e268cd-4ae7-4a15-a0c5-8a8e1d5af611' User entered '24 Sep 2020 00:36'	System	24 Sep 2020 05:36:22
	System	24 Sep 2020 05:36:22

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 3'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:52:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '97e2f021-da8e-4798-8631-b75ae5f88495' User entered 'None (0)'	System	24 Sep 2020 18:52:20
	System	24 Sep 2020 18:52:20

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:52:01', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '97e2f021-da8e-4798-8631-b75ae5f88495' User entered 'None (0)'	System	24 Sep 2020 18:52:20
	System	24 Sep 2020 18:52:20

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:52:02', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '97e2f021-da8e-4798-8631-b75ae5f88495' User entered 'None (0)'	System	24 Sep 2020 18:52:20
	System	24 Sep 2020 18:52:20

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:52:04', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '97e2f021-da8e-4798-8631-b75ae5f88495' User entered 'None (0)'	System	24 Sep 2020 18:52:20
	System	24 Sep 2020 18:52:20

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:52:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '97e2f021-da8e-4798-8631-b75ae5f88495' User entered 'None (0)'	System	24 Sep 2020 18:52:20
	System	24 Sep 2020 18:52:20

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:52:14', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '97e2f021-da8e-4798-8631-b75ae5f88495' User entered 'None (0)'	System	24 Sep 2020 18:52:20
	System	24 Sep 2020 18:52:20

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:52:16', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '97e2f021-da8e-4798-8631-b75ae5f88495' User entered 'No (N)'	System	24 Sep 2020 18:52:20
	System	24 Sep 2020 18:52:20

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-24T13:52:17', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '97e2f021-da8e-4798-8631-b75ae5f88495' User entered '24 Sep 2020 13:52'	System	24 Sep 2020 18:52:20
	System	24 Sep 2020 18:52:20

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 4'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 5'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:02:35', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '36ade16b-3166-410d-a9cb-a17e45dae6b8' User entered 'None (0)'	System	27 Sep 2020 15:02:49
	System	27 Sep 2020 15:02:49

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:02:36', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '36ade16b-3166-410d-a9cb-a17e45dae6b8' User entered 'None (0)'	System	27 Sep 2020 15:02:49
	System	27 Sep 2020 15:02:49

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:02:37', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '36ade16b-3166-410d-a9cb-a17e45dae6b8' User entered 'None (0)'	System	27 Sep 2020 15:02:49
	System	27 Sep 2020 15:02:49

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:02:39', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '36ade16b-3166-410d-a9cb-a17e45dae6b8' User entered 'None (0)'	System	27 Sep 2020 15:02:49
	System	27 Sep 2020 15:02:49

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:02:40', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '36ade16b-3166-410d-a9cb-a17e45dae6b8' User entered 'None (0)'	System	27 Sep 2020 15:02:49
	System	27 Sep 2020 15:02:49

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:02:41', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '36ade16b-3166-410d-a9cb-a17e45dae6b8' User entered 'None (0)'	System	27 Sep 2020 15:02:49
	System	27 Sep 2020 15:02:49

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:02:42', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '36ade16b-3166-410d-a9cb-a17e45dae6b8' User entered 'No (N)'	System	27 Sep 2020 15:02:49
	System	27 Sep 2020 15:02:49

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-27T10:02:44', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '36ade16b-3166-410d-a9cb-a17e45dae6b8' User entered '27 Sep 2020 10:02'	System	27 Sep 2020 15:02:49
	System	27 Sep 2020 15:02:49

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 6'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
Data entry locked.	System	22 Sep 2020 18:54:03
User entered 'Day 7'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:15', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b7af3c73-b020-4422-8a9c-524c7194854c' User entered 'None (0)'	System	29 Sep 2020 11:11:25
	System	29 Sep 2020 11:11:25

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:16', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b7af3c73-b020-4422-8a9c-524c7194854c' User entered 'None (0)'	System	29 Sep 2020 11:11:25
	System	29 Sep 2020 11:11:25

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:17', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b7af3c73-b020-4422-8a9c-524c7194854c' User entered 'None (0)'	System	29 Sep 2020 11:11:25
	System	29 Sep 2020 11:11:25

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:18', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b7af3c73-b020-4422-8a9c-524c7194854c' User entered 'None (0)'	System	29 Sep 2020 11:11:25
	System	29 Sep 2020 11:11:25

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:19', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b7af3c73-b020-4422-8a9c-524c7194854c' User entered 'None (0)'	System	29 Sep 2020 11:11:25
	System	29 Sep 2020 11:11:25

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:20', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b7af3c73-b020-4422-8a9c-524c7194854c' User entered 'None (0)'	System	29 Sep 2020 11:11:25
	System	29 Sep 2020 11:11:25

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

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)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:21', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b7af3c73-b020-4422-8a9c-524c7194854c' User entered 'No (N)'	System	29 Sep 2020 11:11:25
	System	29 Sep 2020 11:11:25

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-09-29T06:11:23', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b7af3c73-b020-4422-8a9c-524c7194854c' User entered '29 Sep 2020 06:11'	System	29 Sep 2020 11:11:25
	System	29 Sep 2020 11:11:25

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 18:54:03

US3032337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:55:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:45
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 18:54:03

US3032337

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:12:18
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	29 Sep 2020 19:24:17

US3032337

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:12:18
User entered '29 Sep 2020'	(b) (4) Samantha Wieseler (b) (4)	29 Sep 2020 19:24:17

US3032337

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:12:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	29 Sep 2020 19:24:17

US3032337

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:12:18
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Sep 2020 19:24:17
	(b) (4)	

US3032337

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:12:18
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	29 Sep 2020 19:24:29

US3032337

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '1'	System	29 Sep 2020 19:24:29

US3032337

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:56:11
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 20:27:52

US3032337

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:56:11
User entered '6 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 20:27:52
	(b) (4)	

US3032337

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:56:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 20:27:52

US3032337

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:56:11
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 20:27:52

US3032337

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:56:11
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 20:27:55

US3032337

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '1'	System	06 Oct 2020 20:27:55

US3032337

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:47:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	13 Oct 2020 20:16:06

US3032337

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:47:55
User entered '13 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	13 Oct 2020 20:16:06
	(b) (4)	

US3032337

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:47:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	13 Oct 2020 20:16:06
	(b) (4)	

US3032337

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:47:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	13 Oct 2020 20:16:06

US3032337

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:47:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 20:16:09

US3032337

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '1'	System	13 Oct 2020 20:16:09

US3032337

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:07:42

US3032337

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:07:42
	(b) (4)	

US3032337

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 21:07:42

US3032337

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'VISIT3'	System	19 Oct 2020 21:07:42

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:17
	(b) (4)	

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:17
	(b) (4)	

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered '15:15'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 21:08:17

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '19 Oct 2020 15:15'	System	19 Oct 2020 21:08:17

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered '37.1' C	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:17

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:17
	(b) (4)	

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:17
	(b) (4)	

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered '80'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:17

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'bpm'	System	19 Oct 2020 21:08:17

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:17

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'breaths/min'	System	19 Oct 2020 21:08:17

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered '108'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:17

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'mmHg'	System	19 Oct 2020 21:08:17

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered '67'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 21:08:17

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'mmHg'	System	19 Oct 2020 21:08:17

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39

US3032337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39

US3032337

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:33

US3032337

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:33
	(b) (4)	

US3032337

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:52
	(b) (4)	

US3032337

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:52
	(b) (4)	

US3032337

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered '15:23'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:52

US3032337

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '19 Oct 2020 15:23'	System	19 Oct 2020 21:08:52

US3032337

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:08:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 21:08:56

US3032337

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered '1'	System	19 Oct 2020 21:08:56

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 64'	System	25 Aug 2020 17:12:57

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-10-26T10:00:26', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'cb8c7527-ee35-4f67-b574-40422d382a56'	System	26 Oct 2020 15:01:41
User entered 'Yes (Y)'	System	26 Oct 2020 15:01:41

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-10-26T10:00:53', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'cb8c7527-ee35-4f67-b574-40422d382a56'	System	26 Oct 2020 15:01:41
User entered 'Yes (Y)'	System	26 Oct 2020 15:01:41

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-10-26T10:00:52', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'cb8c7527-ee35-4f67-b574-40422d382a56'	System	26 Oct 2020 15:01:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Oct 2020 15:01:41

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-10-26T10:01:01', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'cb8c7527-ee35-4f67-b574-40422d382a56'	System	26 Oct 2020 15:01:41
User entered 'No (N)'	System	26 Oct 2020 15:01:41

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-10-26T10:01:11', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'cb8c7527-ee35-4f67-b574-40422d382a56'	System	26 Oct 2020 15:01:41
User entered 'No (N)'	System	26 Oct 2020 15:01:41

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-10-26T10:01:30', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'cb8c7527-ee35-4f67-b574-40422d382a56' User entered '26 Oct 2020 10:01:30'	System	26 Oct 2020 15:01:41
	System	26 Oct 2020 15:01:41

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	25 Aug 2020 17:12:57
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 17:12:57

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	25 Aug 2020 17:12:57
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 71'	System	25 Aug 2020 17:12:57

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-11-03T11:47:40', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '237349f5-db24-496d-8427-0218581db7cc'	System	03 Nov 2020 17:47:53
User entered 'No (N)'	System	03 Nov 2020 17:47:53

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-11-03T11:47:48', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '237349f5-db24-496d-8427-0218581db7cc'	System	03 Nov 2020 17:47:53
User entered 'No (N)'	System	03 Nov 2020 17:47:53

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-11-03T11:47:50', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '237349f5-db24-496d-8427-0218581db7cc' User entered '03 Nov 2020 11:47:50'	System	03 Nov 2020 17:47:53
	System	03 Nov 2020 17:47:53

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	25 Aug 2020 17:12:57
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 17:12:57

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	25 Aug 2020 17:12:57
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	25 Aug 2020 17:12:57
User entered 'Day 78'	System	25 Aug 2020 17:12:57

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-11-10T12:12:44', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '7169293a-a76a-488b-837b-b7564b259991'	System	10 Nov 2020 18:12:56
User entered 'No (N)'	System	10 Nov 2020 18:12:56

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-11-10T12:12:50', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '7169293a-a76a-488b-837b-b7564b259991'	System	10 Nov 2020 18:12:56
User entered 'No (N)'	System	10 Nov 2020 18:12:56

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-11-10T12:12:52', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '7169293a-a76a-488b-837b-b7564b259991' User entered '10 Nov 2020 12:12:52'	System	10 Nov 2020 18:12:56
	System	10 Nov 2020 18:12:56

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	25 Aug 2020 17:12:57
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 17:12:57

US3032337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:12:56
Data entry locked.	System	25 Aug 2020 17:12:57
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 17:12:57

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-11-29T17:59:12', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f2d02778-7573-4b42-a5bd-03b7dd872c4a'	System	29 Nov 2020 23:59:24
User entered 'No (N)'	System	29 Nov 2020 23:59:24

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-11-29T17:59:17', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f2d02778-7573-4b42-a5bd-03b7dd872c4a'	System	29 Nov 2020 23:59:24
User entered 'No (N)'	System	29 Nov 2020 23:59:24

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-11-29T17:59:20', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f2d02778-7573-4b42-a5bd-03b7dd872c4a' User entered '29 Nov 2020 17:59:20'	System	29 Nov 2020 23:59:24
	System	29 Nov 2020 23:59:24

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-03T01:44:49', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a759a19f-fe9f-4f29-b499-0a0014c678f0'	System	03 Dec 2020 07:44:56
User entered 'No (N)'	System	03 Dec 2020 07:44:56

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-03T01:44:51', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a759a19f-fe9f-4f29-b499-0a0014c678f0'	System	03 Dec 2020 07:44:56
User entered 'No (N)'	System	03 Dec 2020 07:44:56

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-03T01:44:53', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a759a19f-fe9f-4f29-b499-0a0014c678f0' User entered '03 Dec 2020 01:44:53'	System	03 Dec 2020 07:44:56
	System	03 Dec 2020 07:44:56

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-11T08:37:57', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '4337dc3b-fd83-4fff-a2cc-caf10f1d8765'	System	11 Dec 2020 14:38:04
User entered 'No (N)'	System	11 Dec 2020 14:38:04

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-11T08:37:59', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '4337dc3b-fd83-4fff-a2cc-caf10f1d8765'	System	11 Dec 2020 14:38:04
User entered 'No (N)'	System	11 Dec 2020 14:38:04

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-11T08:38:02', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '4337dc3b-fd83-4fff-a2cc-caf10f1d8765'	System	11 Dec 2020 14:38:04
User entered '11 Dec 2020 08:38:02'	System	11 Dec 2020 14:38:04

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-17T09:43:45', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '08dfaba9-d9ee-477c-b040-24bc54271262'	System	17 Dec 2020 15:44:04
User entered 'No (N)'	System	17 Dec 2020 15:44:04

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-17T09:43:46', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '08dfaba9-d9ee-477c-b040-24bc54271262'	System	17 Dec 2020 15:44:04
User entered 'No (N)'	System	17 Dec 2020 15:44:04

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-17T09:43:57', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '08dfaba9-d9ee-477c-b040-24bc54271262'	System	17 Dec 2020 15:44:04
User entered '17 Dec 2020 09:43:57'	System	17 Dec 2020 15:44:04

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-24T08:59:58', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered 'Yes (Y)'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-24T08:59:54', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered 'Yes (Y)'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Please 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-24T08:59:52', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:37:51', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered 'Yes (Y)'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '1'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '1'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62' User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62' User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '1'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '0'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Please 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:08', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:12', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered 'No (N)'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2020-12-27T19:38:14', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'edb4478b-d9ce-4d6d-8fca-87d7d3572c62'	System	28 Dec 2020 01:38:27
User entered '27 Dec 2020 19:38:14'	System	28 Dec 2020 01:38:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-01-01T12:29:38', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '08b21c64-5508-45e8-9392-40bf8a79f109'	System	01 Jan 2021 18:29:45
User entered 'No (N)'	System	01 Jan 2021 18:29:45

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-01-01T12:29:41', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '08b21c64-5508-45e8-9392-40bf8a79f109'	System	01 Jan 2021 18:29:45
User entered 'No (N)'	System	01 Jan 2021 18:29:45

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-01-01T12:29:43', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '08b21c64-5508-45e8-9392-40bf8a79f109'	System	01 Jan 2021 18:29:45
User entered '01 Jan 2021 12:29:43'	System	01 Jan 2021 18:29:45

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-01-09T12:03:45', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '8b3f1d63-1be9-4918-b2d8-506ee809ef16'	System	09 Jan 2021 18:03:51
User entered 'No (N)'	System	09 Jan 2021 18:03:51

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-01-09T12:03:47', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '8b3f1d63-1be9-4918-b2d8-506ee809ef16'	System	09 Jan 2021 18:03:51
User entered 'No (N)'	System	09 Jan 2021 18:03:51

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-01-09T12:03:49', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '8b3f1d63-1be9-4918-b2d8-506ee809ef16'	System	09 Jan 2021 18:03:51
User entered '09 Jan 2021 12:03:49'	System	09 Jan 2021 18:03:51

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-01-15T02:12:49', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '5bb659c7-c6c4-46a7-afcf-a947050ae581' User entered 'No (N)'	System	15 Jan 2021 08:12:54
	System	15 Jan 2021 08:12:54

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-01-15T02:12:50', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '5bb659c7-c6c4-46a7-afcf-a947050ae581'	System	15 Jan 2021 08:12:54
User entered 'No (N)'	System	15 Jan 2021 08:12:54

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-01-15T02:12:52', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '5bb659c7-c6c4-46a7-afcf-a947050ae581' User entered '15 Jan 2021 02:12:52'	System	15 Jan 2021 08:12:54
	System	15 Jan 2021 08:12:54

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-01-28T09:09:38', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2d2517ae-f52c-4e25-acde-629366a065a7'	System	28 Jan 2021 15:09:59
User entered 'No (N)'	System	28 Jan 2021 15:09:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-01-28T09:09:39', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2d2517ae-f52c-4e25-acde-629366a065a7'	System	28 Jan 2021 15:09:59
User entered 'No (N)'	System	28 Jan 2021 15:09:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-01-28T09:09:41', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2d2517ae-f52c-4e25-acde-629366a065a7' User entered '28 Jan 2021 09:09:41'	System	28 Jan 2021 15:09:59
	System	28 Jan 2021 15:09:59

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-04T11:13:28', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'fb4b41df-506b-4ca7-9e1b-039c1aeaa5b'	System	04 Feb 2021 17:14:25
User entered 'No (N)'	System	04 Feb 2021 17:14:25

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-04T11:13:30', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'fb4b41df-506b-4ca7-9e1b-039c1aeaa5b'	System	04 Feb 2021 17:14:25
User entered 'No (N)'	System	04 Feb 2021 17:14:25

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-04T11:13:31', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'fb4b41df-506b-4ca7-9e1b-039c1aeaa5b' User entered '04 Feb 2021 11:13:31'	System	04 Feb 2021 17:14:25
	System	04 Feb 2021 17:14:25

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:01:22', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f'	System	11 Feb 2021 06:02:30
User entered 'Yes (Y)'	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:01:28', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered 'No (N)'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:01:37', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f'	System	11 Feb 2021 06:02:30
User entered 'Yes (Y)'	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '0'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '1'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '1'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '1'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '0'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '0'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '0'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '0'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '0'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '0'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '0'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '1'	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '0'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '0'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '0'	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '0'	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:06', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '0'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Please 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:09', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f'	System	11 Feb 2021 06:02:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:13', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered 'No (N)'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-11T00:02:15', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b9832020-1f8c-4a95-aec4-83608037f92f' User entered '11 Feb 2021 00:02:15'	System	11 Feb 2021 06:02:30
	System	11 Feb 2021 06:02:30

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-18T00:04:17', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '72e15bff-1ca3-4a56-8699-5ce6343e4c55'	System	18 Feb 2021 06:04:26
User entered 'No (N)'	System	18 Feb 2021 06:04:26

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-18T00:04:20', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '72e15bff-1ca3-4a56-8699-5ce6343e4c55'	System	18 Feb 2021 06:04:26
User entered 'No (N)'	System	18 Feb 2021 06:04:26

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-18T00:04:22', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '72e15bff-1ca3-4a56-8699-5ce6343e4c55'	System	18 Feb 2021 06:04:26
User entered '18 Feb 2021 00:04:22'	System	18 Feb 2021 06:04:26

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-25T00:17:52-06:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '64a739ee-f4ad-44de-a284-0713ec2f9b13'	System	25 Feb 2021 06:18:01
User entered 'No (N)'	System	25 Feb 2021 06:18:01

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-25T00:17:54-06:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '64a739ee-f4ad-44de-a284-0713ec2f9b13'	System	25 Feb 2021 06:18:01
User entered 'No (N)'	System	25 Feb 2021 06:18:01

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-02-25T00:17:56-06:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '64a739ee-f4ad-44de-a284-0713ec2f9b13'	System	25 Feb 2021 06:18:01
User entered '25 Feb 2021 06:17:56'	System	25 Feb 2021 06:18:01

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-04T06:43:49-06:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'e7b609c5-a59d-4ee9-a4ab-bc39f8f03cbc'	System	04 Mar 2021 12:44:10
User entered 'No (N)'	System	04 Mar 2021 12:44:10

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-04T06:43:50-06:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'e7b609c5-a59d-4ee9-a4ab-bc39f8f03cbc'	System	04 Mar 2021 12:44:10
User entered 'No (N)'	System	04 Mar 2021 12:44:10

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-04T06:43:52-06:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'e7b609c5-a59d-4ee9-a4ab-bc39f8f03cbc' User entered '04 Mar 2021 06:43:52'	System	04 Mar 2021 12:44:10
	System	04 Mar 2021 12:44:10

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-11T00:02:21-06:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b8f26b38-dab9-4982-bea1-7fe9b35e5e44'	System	11 Mar 2021 06:02:27
User entered 'No (N)'	System	11 Mar 2021 06:02:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-11T00:02:22-06:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b8f26b38-dab9-4982-bea1-7fe9b35e5e44'	System	11 Mar 2021 06:02:27
User entered 'No (N)'	System	11 Mar 2021 06:02:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-11T00:02:24-06:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'b8f26b38-dab9-4982-bea1-7fe9b35e5e44' User entered '11 Mar 2021 00:02:24'	System	11 Mar 2021 06:02:27
	System	11 Mar 2021 06:02:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-18T11:07:32-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '83b096bb-86bd-45b0-b53b-55e7ce06cad4'	System	18 Mar 2021 16:13:25
User entered 'No (N)'	System	18 Mar 2021 16:13:25

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-18T11:07:33-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '83b096bb-86bd-45b0-b53b-55e7ce06cad4'	System	18 Mar 2021 16:13:25
User entered 'No (N)'	System	18 Mar 2021 16:13:25

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-18T11:07:35-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '83b096bb-86bd-45b0-b53b-55e7ce06cad4'	System	18 Mar 2021 16:13:25
User entered '18 Mar 2021 11:07:35'	System	18 Mar 2021 16:13:25

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-25T00:02:51-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f4256eac-9769-47c9-b4a4-0256a657517f' User entered 'No (N)'	System	25 Mar 2021 05:02:58
	System	25 Mar 2021 05:02:58

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-25T00:02:53-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f4256eac-9769-47c9-b4a4-0256a657517f' User entered 'No (N)'	System	25 Mar 2021 05:02:58
	System	25 Mar 2021 05:02:58

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-25T00:02:54-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'f4256eac-9769-47c9-b4a4-0256a657517f' User entered '25 Mar 2021 00:02:54'	System	25 Mar 2021 05:02:58
	System	25 Mar 2021 05:02:58

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-01T00:02:55-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2c613fac-5a75-46f5-9e94-317f1eab59fe'	System	01 Apr 2021 05:03:01
User entered 'No (N)'	System	01 Apr 2021 05:03:01

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-01T00:02:56-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2c613fac-5a75-46f5-9e94-317f1eab59fe'	System	01 Apr 2021 05:03:01
User entered 'No (N)'	System	01 Apr 2021 05:03:01

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-01T00:02:58-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2c613fac-5a75-46f5-9e94-317f1eab59fe'	System	01 Apr 2021 05:03:01
User entered '01 Apr 2021 00:02:58'	System	01 Apr 2021 05:03:01

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-08T03:57:32-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a9893543-fe28-4f96-a1fb-5e5e6a5f77d6'	System	08 Apr 2021 08:57:37
User entered 'No (N)'	System	08 Apr 2021 08:57:37

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-08T03:57:33-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a9893543-fe28-4f96-a1fb-5e5e6a5f77d6'	System	08 Apr 2021 08:57:37
User entered 'No (N)'	System	08 Apr 2021 08:57:37

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-08T03:57:35-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'a9893543-fe28-4f96-a1fb-5e5e6a5f77d6'	System	08 Apr 2021 08:57:37
User entered '08 Apr 2021 03:57:35'	System	08 Apr 2021 08:57:37

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-15T00:03:02-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'd65f9dd9-33ba-405d-9c17-665f6213186a'	System	15 Apr 2021 05:03:52
User entered 'No (N)'	System	15 Apr 2021 05:03:52

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-15T00:03:03-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'd65f9dd9-33ba-405d-9c17-665f6213186a' User entered 'No (N)'	System	15 Apr 2021 05:03:52
	System	15 Apr 2021 05:03:52

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-15T00:03:05-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'd65f9dd9-33ba-405d-9c17-665f6213186a'	System	15 Apr 2021 05:03:52
User entered '15 Apr 2021 00:03:05'	System	15 Apr 2021 05:03:52

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-24T12:06:14-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'ccb49c05-82e2-4857-95ba-aba30f947113'	System	24 Apr 2021 17:06:27
User entered 'No (N)'	System	24 Apr 2021 17:06:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-24T12:06:15-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'ccb49c05-82e2-4857-95ba-aba30f947113'	System	24 Apr 2021 17:06:27
User entered 'No (N)'	System	24 Apr 2021 17:06:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-24T12:06:23-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'ccb49c05-82e2-4857-95ba-aba30f947113'	System	24 Apr 2021 17:06:27
User entered '24 Apr 2021 12:06:23'	System	24 Apr 2021 17:06:27

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-29T00:40:26-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2ef47681-d591-4d2a-ad7d-039c4912c57e' User entered 'No (N)'	System	29 Apr 2021 05:40:34
	System	29 Apr 2021 05:40:34

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

Have you been exposed to someone with 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 (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-29T00:40:28-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2ef47681-d591-4d2a-ad7d-039c4912c57e'	System	29 Apr 2021 05:40:34
User entered 'No (N)'	System	29 Apr 2021 05:40:34

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-04-29T00:40:31-05:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: '2ef47681-d591-4d2a-ad7d-039c4912c57e' User entered '29 Apr 2021 00:40:31'	System	29 Apr 2021 05:40:34
	System	29 Apr 2021 05:40:34

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 17:23:48

US3032337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:23:48
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 17:23:48

US3032337

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:55:34

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)	24 Apr 2021 12:24:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-04T06:43:59-06:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'cc882c60-21b3-4cc2-bfce-4218307a6a63'	System	04 Mar 2021 12:44:21
User entered 'No (N)'	System	04 Mar 2021 12:44:21

US3032337

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:55:34

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:24:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55ED7C99-5482-4F06-951B-C59A4B25E666)', Time: '2021-03-04T06:44:01-06:00', User OID: 'PatientReportedOutcome (US3032337)', ODM File OID: 'cc882c60-21b3-4cc2-bfce-4218307a6a63' User entered '04 Mar 2021 06:44:01'	System	04 Mar 2021 12:44:21
	System	04 Mar 2021 12:44:21

US3032337

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:54:04
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	16 Nov 2020 15:09:57

US3032337

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:54:04
User entered '16 Nov 2020'	Samantha Wieseler (b) (4)	16 Nov 2020 15:09:57

US3032337

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:54:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	16 Nov 2020 15:09:57

US3032337

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:54:04
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	16 Nov 2020 15:09:57
	(b) (4)	

US3032337

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:54:04
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	16 Nov 2020 15:10:00

US3032337

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:46:39
User entered 'I'	System	16 Nov 2020 15:10:00

US3032337

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:57:09
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	18 Dec 2020 14:45:16

US3032337

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:57:09
User entered '18 Dec 2020'	Samantha Wieseler (b) (4)	18 Dec 2020 14:45:16

US3032337

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:57:09
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4)	18 Dec 2020 14:45:16

US3032337

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:57:09
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Dec 2020 14:45:16
	(b) (4)	

US3032337

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:57:09
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	18 Dec 2020 14:45:19

US3032337

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User entered '1'	System	18 Dec 2020 14:45:19

US3032337

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:48:16
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	16 Mar 2021 17:13:00

US3032337

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:48:16
User entered '18 Jan 2021'	(b) (4) Linden DeBoer (b) (4)	16 Mar 2021 17:13:00
	(b) (4)	

US3032337

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:48:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4)	16 Mar 2021 17:13:00

US3032337

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:48:16
User entered empty.	(b) (4) Linden DeBoer (b) (4)	16 Mar 2021 17:13:00

US3032337

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:48:16
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	16 Mar 2021 17:13:19

US3032337

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User entered 'I'	System	16 Mar 2021 17:13:19

US3032337

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:48:16
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	16 Mar 2021 17:13:36

US3032337

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:48:16
User entered '16 Feb 2021'	(b) (4) Linden DeBoer (b) (4)	16 Mar 2021 17:13:36
	(b) (4)	

US3032337

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:48:16
User entered 'Contact Made (CONTACT MADE)'	Linden DeBoer (b) (4)	16 Mar 2021 17:13:36

US3032337

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:48:16
User entered empty.	Linden DeBoer (b) (4)	16 Mar 2021 17:13:36

US3032337

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:48:16
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	16 Mar 2021 17:13:43

US3032337

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User entered 'I'	System	16 Mar 2021 17:13:43

US3032337

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User closed query 'Per CDM: Please record vital signs assessed as Yes or No. Otherwise clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 01:51:26
Query 'Per CDM: Please record vital signs assessed as Yes or No. Otherwise clarify. Thank you.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 19:47:12
User opened query 'Per CDM: Please record vital signs assessed as Yes or No. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:05:08
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	18 Mar 2021 22:46:01

US3032337

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '18 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:46:01

US3032337

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Mar 2021 22:46:01

US3032337

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User entered 'VISIT4'	System	18 Mar 2021 22:46:01

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User entered empty.	System	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User entered empty.	System	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User entered empty.	System	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User entered empty.	System	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User entered empty.	System	30 Mar 2021 19:47:26

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09

US3032337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09

US3032337

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:46:12

US3032337

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:46:12
	(b) (4)	

US3032337

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:46:21

US3032337

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '18 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:46:21

US3032337

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '16:32'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:46:21

US3032337

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User entered '18 Mar 2021 16:32'	System	18 Mar 2021 22:46:21

US3032337

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:46:24

US3032337

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:09
User entered '1'	System	18 Mar 2021 22:46:24

US3032337

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:25:54
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	21 Apr 2021 21:38:03
	(b) (4)	

US3032337

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:25:54
	(b) (4)	
User entered '21 Apr 2021'	Samantha Wieseler (b) (4)	21 Apr 2021 21:38:03
	(b) (4)	

US3032337

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:25:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	21 Apr 2021 21:38:03
	(b) (4)	

US3032337

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:25:54
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	21 Apr 2021 21:38:03
	(b) (4)	

US3032337

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:25:54
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	21 Apr 2021 21:37:52
	(b) (4)	

US3032337

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 21:37:52

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:34

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:44
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '30 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:06:38
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:34

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:44
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '09:22'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:06:38

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:34

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:44
User entered '30 Dec 2020 09:22'	System	30 Dec 2020 21:06:38

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Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:34

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:44
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:06:38

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Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:34

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:44
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:06:38

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Day 1 (Day 1)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:06:54

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '27 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:06:54

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '1'	Kelsey Kelley (b) (4)	30 Dec 2020 21:06:54

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered empty.	System	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	Kelsey Kelley (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	Kelsey Kelley (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:06:54

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:06:54

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:06:54

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Day 2 (Day 2)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '28 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '1'	Kelsey Kelley (b) (4)	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered empty.	System	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:02

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:02

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:02

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Day 3 (Day 3)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:22

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '29 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '1'	Kelsey Kelley (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	Kelsey Kelley (b) (4)	30 Dec 2020 21:07:22

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered empty.	System	30 Dec 2020 21:07:22

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:22

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:22

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:22

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Day 4 (Day 4)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '30 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '99'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 21:07:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Day 5 (Day 5)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '31 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '98'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '97.5' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:18

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Day 6 (Day 6)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '1 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '98'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '98.6' F	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:04:57

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Day 7 (Day 7)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:07:16

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '2 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '0'	Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '98'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '97.7' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:16

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Day 8 (Day 8)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '03 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '0'	Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '99'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '97.3' F	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:07:56

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:07:56
	(b) (4)	

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Day 9 (Day 9)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:33:39

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Form: Symptom Log (9)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '4 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39
	(b) (4)	

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Form: Symptom Log (9)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '98'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	08 Jan 2021 00:33:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '97.0' F	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:33:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39
	(b) (4)	

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Form: Symptom Log (9)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:33:39

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39

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Folder: Covid-19 Assessment 30 Dec 2020

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Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:33:39
	(b) (4)	

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Day 10 (Day 10)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:22

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '5 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:22
	(b) (4)	

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:22

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Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '98'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:22

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	08 Jan 2021 00:34:22

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '98.1' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:22

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:22
	(b) (4)	

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Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:22

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:22

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:22

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:22
	(b) (4)	

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:22

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:22
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:22
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:22
	(b) (4)	

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:22
	(b) (4)	

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Form: Symptom Log (10)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:22

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:22
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:22
	(b) (4)	

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Form: Symptom Log (10)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:22
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:22

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Folder: Covid-19 Assessment 30 Dec 2020

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:22

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Day 11 (Day 11)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:46

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '6 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:46

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:46

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '99'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:46

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Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	08 Jan 2021 00:34:46

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Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '97.7' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:46

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:46
	(b) (4)	

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Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:46

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:46

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Folder: Covid-19 Assessment 30 Dec 2020

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:46

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Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:46
	(b) (4)	

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Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:46
	(b) (4)	

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Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:46
	(b) (4)	

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Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:46

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:46

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Form: Symptom Log (11)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:46
	(b) (4)	

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:46

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:46
	(b) (4)	

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Form: Symptom Log (11)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:46
	(b) (4)	

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Form: Symptom Log (11)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:34:46

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Form: Symptom Log (11)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:46
	(b) (4)	

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Form: Symptom Log (11)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	08 Jan 2021 00:34:46
	(b) (4)	

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Form: Symptom Log (12)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Day 12 (Day 12)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '7 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '0'	Kelsey Kelley (b) (4)	12 Jan 2021 15:27:20

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Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '100'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:20

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	12 Jan 2021 15:27:20

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '97.8' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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Form: Symptom Log (12)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

US3032337

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:20
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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Form: Symptom Log (12)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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Form: Symptom Log (12)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:20
	(b) (4)	

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:20

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Day 13 (Day 13)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '8 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:59
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '98'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '97.3' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:59
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:59
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:59
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:59
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:59
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:59
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:27:59

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Day 14 (Day 14)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '9 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '98'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '97.3' F	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:28:39
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:28:39
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:28:39
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:28:39
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:28:39

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Day 15 (Day 15)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '10 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '99'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '98.3' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:55:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:11

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Day 16 (Day 16)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:30:43

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Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '11 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:30:43

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '0'	Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '99'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:30:43

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Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	12 Jan 2021 15:30:43

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Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '97.3' F	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:30:43

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:30:43

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43
	(b) (4)	

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Form: Symptom Log (16)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 15:30:43

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:55:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 15:30:43

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Generated On: 09 Jun 2021 14:55:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'Day 17 (Day 17)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:43:13

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '12 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:43:13

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:43:13

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '99'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:43:13

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User entered '%'	System	18 Jan 2021 15:43:13

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered '97.8' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:43:13

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:55:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:43:13

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Generated On: 09 Jun 2021 14:55:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	18 Jan 2021 15:43:13
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:55:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:43:13

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Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:55:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	18 Jan 2021 15:43:13
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:55:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:43:13

US3032337

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Form: Symptom Log (17)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	18 Jan 2021 15:43:13
	(b) (4)	

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Form: Symptom Log (17)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	18 Jan 2021 15:43:13

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:43:13

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:43:13

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:43:13

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	18 Jan 2021 15:43:13
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	18 Jan 2021 15:43:13
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:55:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	18 Jan 2021 15:43:13
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:55:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	18 Jan 2021 15:43:13
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:55:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	18 Jan 2021 15:43:13
	(b) (4)	

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:55:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:43:13

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:34

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:57
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 30DEC2020 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4)	22 Jan 2021 07:05:44
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 30DEC2020 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'will update accordingly' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	20 Jan 2021 00:12:33
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 30DEC2020 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 10:20:52
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	07 Jan 2021 19:18:26
User entered '30 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:03:15

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:34

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:03:15

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:34

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:03:15

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:34

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:57
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, However please provide both Accession number, Requisition kit id and the shipment tracking details in the response. Thank you.' (Site from DM).		07 Apr 2021 03:40:30
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, However please provide both Accession number, Requisition kit id and the shipment tracking details in the response. Thank you.' answered with 'accession Number: 1F60B9X' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	31 Mar 2021 13:07:05
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, However please provide both Accession number, Requisition kit id and the shipment tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 09:53:53
User closed query 'Per GCL Lab Reconciliation query: Swab: Per response, "will update when update is available."; however, corresponding updates are not reflected in Preclarus portal. Kindly consider providing accession, tracking number and shipped date. Thank you.' (Site from DM).		31 Mar 2021 09:53:53
Query 'Per GCL Lab Reconciliation query: Swab: Per response, "will update when update is available."; however, corresponding updates are not reflected in Preclarus portal. Kindly consider providing accession, tracking number and shipped date. Thank you.' answered with 'Accession Number: 1F60B9X report was received 09Jan2021' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 16:46:32
User opened query 'Per GCL Lab Reconciliation query: Swab: Per response, "will update when update is available."; however, corresponding updates are not reflected in Preclarus portal. Kindly consider providing accession, tracking number and shipped date. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 11:19:40

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:34

[Date of Test](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 30DEC2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 05:52:06
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 30DEC2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'will update when update is available' (Site from DM).	Samantha Wieseler (b) (4)	11 Feb 2021 22:48:26
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 30DEC2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered '30 Dec 2020'	Kelsey Kelley (b) (4)	04 Jan 2021 15:03:15

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:34

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:03:15

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:34

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:03:15

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:34

[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)	29 Apr 2021 00:02:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:03:15

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:34

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	04 Jan 2021 15:03:15

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:34

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	04 Jan 2021 15:03:15

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:34

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:02:57
User entered '0'	System	04 Jan 2021 15:03:15

US3032337

Folder: Covid-19 Assessment 30 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:55:34

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:03:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
User entered 'No (N)'	Kelsey Kelley (b) (4)	30 Dec 2020 21:06:42

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:55:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:35:44

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:55:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	08 Jan 2021 00:35:44
	(b) (4)	

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:55:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
	(b) (4)	
User entered '01 Jan 2021'	Kelsey Kelley (b) (4)	08 Jan 2021 00:35:44
	(b) (4)	

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:55:34

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day5 sample with Accession # 1F634101328 is reported with 03jan2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus . Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 11:54:56
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day5 sample with Accession # 1F634101328 is reported with 03jan2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus . Thank you.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4)	11 Feb 2021 22:48:59
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day5 sample with Accession # 1F634101328 is reported with 03jan2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus . Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:56:08
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F619457770 is reported with 20DEC2020 Date of Collection however, Day 5 in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus . Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:53:53
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F619457770 is reported with 20DEC2020 Date of Collection however, Day 5 in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus . Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:53:46
User accepted default value 'Day 5 (Day 5)'	Kelsey Kelley (b) (4)	08 Jan 2021 00:35:44

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:55:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:58:19
	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	11 Feb 2021 22:48:54
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	11 Feb 2021 22:48:54
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	08 Jan 2021 00:35:44
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:55:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:58:19
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	11 Feb 2021 22:48:54
	(b) (4)	
User entered '03 Jan 2021' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	11 Feb 2021 22:48:54
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	08 Jan 2021 00:35:44
	(b) (4)	

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:55:34

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day7 sample with Accession # 1F637767248 is reported with 05jan2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus . Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 11:55:05
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day7 sample with Accession # 1F637767248 is reported with 05jan2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus . Thank you. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:49:29
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day7 sample with Accession # 1F637767248 is reported with 05jan2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus . Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:57:00
User accepted default value 'Day 7 (Day 7)'	Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:35:44

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:55:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:58:19
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:49:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:49:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:32:10
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:35:44

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:55:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:58:19
	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	11 Feb 2021 22:49:23
	(b) (4)	
User entered '05 Jan 2021' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	11 Feb 2021 22:49:23
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	08 Jan 2021 00:35:44
	(b) (4)	

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:55:34

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F622019614 is reported with 07jan2020 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus . Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 11:55:09
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F622019614 is reported with 07jan2020 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus . Thank you.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4)	11 Feb 2021 22:49:47
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F622019614 is reported with 07jan2020 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus . Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:58:09
User accepted default value 'Day 9 (Day 9)'	Kelsey Kelley (b) (4)	08 Jan 2021 00:35:44

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:55:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:58:19
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:49:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:49:42
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:32:10
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:35:44

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:55:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:58:19
	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	11 Feb 2021 22:49:42
	(b) (4)	
User entered '07 Jan 2021' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	11 Feb 2021 22:49:42
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	08 Jan 2021 00:35:44
	(b) (4)	

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:55:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:35:44

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:55:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Kelsey Kelley (b) (4)	18 Jan 2021 15:41:01
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	08 Jan 2021 00:35:44
	(b) (4)	

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:55:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
	(b) (4)	
User entered '12 Jan 2021' reason for change: New Information	Kelsey Kelley (b) (4)	18 Jan 2021 15:41:01
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	08 Jan 2021 00:35:44
	(b) (4)	

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:55:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:35:44

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:55:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	08 Jan 2021 00:35:44
	(b) (4)	

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:55:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:32:10
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:35:44

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:55:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Kelsey Kelley (b) (4) (b) (4)	08 Jan 2021 00:35:44

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:55:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	08 Jan 2021 00:35:44
	(b) (4)	

US3032337

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:55:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:32:10
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	08 Jan 2021 00:35:44
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:06
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered '30 Dec 2020'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:06
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:06
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	30 Dec 2020 21:05:06

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:36
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered '30 Dec 2020'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:36
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered '13:16'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:36
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
User entered '30 Dec 2020 13:16'	System	30 Dec 2020 21:05:36

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered missing code ND - Not Done.	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:36
	(b) (4)	
DataPoint set to visible.	System	30 Dec 2020 21:05:06

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered missing code ND - Not Done.	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:36
	(b) (4)	
DataPoint set to visible.	System	30 Dec 2020 21:05:06

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered '36.7' C	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:36
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:36
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:36
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered '77'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:36
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Dec 2020 21:05:36

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered '14'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:36
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Dec 2020 21:05:36

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered '112'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:36
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Dec 2020 21:05:36

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered '80'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:36
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Dec 2020 21:05:36

US3032337

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:41
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:18:26
	(b) (4)	
User entered '30 Dec 2020'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:41
	(b) (4)	

US3032337

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:55:34

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2: Re-Query: As per the response "PPD will be updated" Still there is no collection date got updated for the Preclarus Requisition kit id 1F640728207 for Illness visit in PPD central lab. Please review the Preclarus and update the missing Date of collection' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:17:58
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Re-Query: As per the response "PPD will be updated" Still there is no collection date got updated for the Preclarus Requisition kit id 1F640728207 for Illness visit in PPD central lab. Please review the Preclarus and update the missing Date of collection' answered with 'will update where update is needed' (Site from DM).	Samantha Wieseler (b) (4)	29 Mar 2021 14:49:57
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: Re-Query: As per the response "PPD will be updated" Still there is no collection date got updated for the Preclarus Requisition kit id 1F640728207 for Illness visit in PPD central lab. Please review the Preclarus and update the missing Date of collection' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:56:20
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2: Re-Query: As per the response "that is the right collection" If sample is collected with missing collection date with Preclarus Requisition kit id 1F640728207 as Illness visit in PPD central lab then Please review the Preclarus and update the missing Date of collection.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:56:20
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Re-Query: As per the response "that is the right collection" If sample is collected with missing collection date with Preclarus Requisition kit id 1F640728207 as Illness visit in PPD central lab then Please review the Preclarus and update the missing Date of collection.' answered with 'PPD will be updated ' (Site from DM).	Samantha Wieseler (b) (4)	26 Mar 2021 13:58:06

US3032337

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:55:34

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: Re-Query: As per the response "that is the right collection" If sample is collected with missing collection date with Preclarus Requisition kit id 1F640728207 as Illness visit in PPD central lab then Please review the Preclarus and update the missing Date of collection.' (Site from DM). User closed query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample which received at 10 FEB 2021 with Preclarus Requisition kit id 1F640728207 as Illness visit with Missing date of collection. Please review the Preclarus and update the missing Date of collection. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 05:33:41 24 Mar 2021 05:33:41
Query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample which received at 10 FEB 2021 with Preclarus Requisition kit id 1F640728207 as Illness visit with Missing date of collection. Please review the Preclarus and update the missing Date of collection. ' answered with 'that is the right collection ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	23 Mar 2021 17:13:19
User opened query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample which received at 10 FEB 2021 with Preclarus Requisition kit id 1F640728207 as Illness visit with Missing date of collection. Please review the Preclarus and update the missing Date of collection. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 06:26:14
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Feb 2021 19:42:38
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	30 Dec 2020 21:05:49

US3032337

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:55:34

Date of Collection

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 30 DEC 2020 is reported under illness visit Day 1 in EDC, however the same SARS-CoV-2 serum sample collection date is missing under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date, update as appropriate in Preclarus . Else Clarify, Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 07:18:58
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 30 DEC 2020 is reported under illness visit Day 1 in EDC, however the same SARS-CoV-2 serum sample collection date is missing under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date, update as appropriate in Preclarus . Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 06:01:32
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for providing the Accession number (1F60B9X) , Please also provide the Tracking number with the shipping date for the 30 DEC 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 04:52:15
Query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for providing the Accession number (1F60B9X) , Please also provide the Tracking number with the shipping date for the 30 DEC 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD. ' answered with 'will update when update is available' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	17 Feb 2021 20:01:16

US3032337

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:55:34

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for response, please provide the Accession number and Tracking number with the shipping date for the 30 DEC 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1 in EDC to track the sample in PPD central lab as the sample is still missing in PPD.' (Site from DM). User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for providing the Accession number (1F60B9X) , Please also provide the Tracking number with the shipping date for the 30 DEC 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:37:08 16 Feb 2021 05:37:03
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for response, please provide the Accession number and Tracking number with the shipping date for the 30 DEC 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1 in EDC to track the sample in PPD central lab as the sample is still missing in PPD.' answered with 'Accession Number: 1F60B9X ' ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:50:34
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for response, please provide the Accession number and Tracking number with the shipping date for the 30 DEC 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1 in EDC to track the sample in PPD central lab as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 04:32:30

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Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:55:34

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per Lab Recon: SARS-COV2: Re-Query: Thank you for the response, however SARS sample dated 30 DEC 2020, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	08 Feb 2021 04:32:30
Query 'Per Lab Recon: SARS-COV2: Re-Query: Thank you for the response, however SARS sample dated 30 DEC 2020, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'will update accordingly' (Site from DM).	Keith Vrbicky (b) (4) (b) (4)	05 Feb 2021 19:42:38
User opened query 'Per Lab Recon: SARS-COV2: Re-Query: Thank you for the response, however SARS sample dated 30 DEC 2020, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	01 Feb 2021 22:47:09
User opened query 'Per Lab Recon: SARS-COV2: Re-Query: Thank you for the response, however SARS sample dated 30 DEC 2020, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 07:58:01

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Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:55:34

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 30 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 15:30:41
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 30 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'will update accordingly' (Site from DM).	Samantha Wieseler (b) (4)	20 Jan 2021 00:12:54
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 30 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 12:14:59
User entered '30 Dec 2020'	Kelsey Kelley (b) (4)	30 Dec 2020 21:05:49

US3032337

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

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:50:51

US3032337

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

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '18 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:50:51

US3032337

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

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Mar 2021 22:50:51

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

Form: Visit Date

Generated On: 09 Jun 2021 14:55:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered 'UNBLND_DECIDE'	System	18 Mar 2021 22:50:51

US3032337

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:34

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '18 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:07
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:34

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:07

US3032337

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:34

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:07

US3032337

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:34

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:07

US3032337

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:34

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '18 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:07
	(b) (4)	

US3032337

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:34

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:07
	(b) (4)	

US3032337

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:34

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:07
	(b) (4)	

US3032337

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:34

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:07
	(b) (4)	

US3032337

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:34

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:07

US3032337

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:34

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered empty.	System	18 Mar 2021 22:51:07

US3032337

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

Form: Unblinding

Generated On: 09 Jun 2021 14:55:34

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered empty.	System	18 Mar 2021 22:51:07

US3032337

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:20
	(b) (4)	

US3032337

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '18 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:20
	(b) (4)	

US3032337

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '16:32'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Mar 2021 22:51:20

US3032337

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered '18 Mar 2021 16:32'	System	18 Mar 2021 22:51:20

US3032337

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:55:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:27
	(b) (4)	

US3032337

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:55:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '18 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:27
	(b) (4)	

US3032337

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:55:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '16:37'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:51:27
	(b) (4)	

US3032337

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:22:36
User entered '18 Mar 2021 16:37'	System	18 Mar 2021 22:51:27

US3032337

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:55:34

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:12
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Signature has been broken.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:01:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:01:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	15 Sep 2020 22:51:07

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User closed query 'Per MM: Please update to the underlying diagnosis. ' (Site from DM).		21 Apr 2021 00:54:18
Query 'Per MM: Please update to the underlying diagnosis. ' answered with 'will update if necessary' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	12 Apr 2021 14:19:23
User opened query 'Per MM: Please update to the underlying diagnosis. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:29:11
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Nervous system disorders NEC, PT: Central nervous system lesion, LLT: Central nervous system lesion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:21:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:21:32
Data point term sent to Coder System		18 Mar 2021 22:03:41
User entered 'Intracranial space-occupying lesion found on diagnostic imaging of central nervous system.'	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User entered empty.	System	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 19:17:23
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	01 Apr 2021 19:17:29
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	01 Apr 2021 19:17:29
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Apr 2021 19:17:23
User entered '14 Mar 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	01 Apr 2021 19:17:23
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User entered empty.	System	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '1'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 19:17:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

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 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User entered '0'	System	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49
User entered '1'	System	18 Mar 2021 22:02:50

US3032337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:49

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Mar 2021 15:57:00
Un-reviewed for Safety.		29 Mar 2021 15:56:56
Reviewed for Safety.		19 Mar 2021 16:48:04
User entered 'USA-US032-2021-mRNA-1273-P301000011'	System	19 Mar 2021 16:47:59
User entered 'New'	(b) (4), (b) (6)	19 Mar 2021 16:47:59

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User coded data point as SOC: Nervous system disorders, HLG: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizure - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	18 Mar 2021 22:05:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Mar 2021 22:05:42
Data point term sent to Coder	System	18 Mar 2021 22:04:42
User entered 'Seizure'	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:03:52

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:03:52

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'No (N)'	Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:03:52

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 22:03:52

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:03:52

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 22:03:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	18 Mar 2021 22:05:09
	(b) (4)	
User entered 'No (N)'	Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:03:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:03:52

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:03:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	18 Mar 2021 22:05:09
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered '1'	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:03:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '1'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	(b) (4)	01 Apr 2021 19:46:51
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	01 Apr 2021 19:46:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Kelsey Kelley (b) (4)	01 Apr 2021 19:46:37
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	(b) (4)	18 Mar 2021 22:03:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	01 Apr 2021 19:46:51
	(b) (4)	
User entered 'Subject has a brain bleed.'	Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: It was reported that the urban hospital reviewed CT of Head to find no bleeding or calcifications. Please clarify if this was same day that ER found bleeding on CT. Was a second CT scan done at the urban hospital?' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:18:58
Query 'PV Query: It was reported that the urban hospital reviewed CT of Head to find no bleeding or calcifications. Please clarify if this was same day that ER found bleeding on CT. Was a second CT scan done at the urban hospital?' answered with 'This was completed same day. The original CT was performed at the rural hospital. At the urban hospital an overread was completed which in which findings did NOT show bleeding. An MRI of the head was completed at the urban hospital to verify results were negative for bleeding/calcifications. ' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	09 Apr 2021 21:38:05
User opened query 'PV Query: It was reported that the urban hospital reviewed CT of Head to find no bleeding or calcifications. Please clarify if this was same day that ER found bleeding on CT. Was a second CT scan done at the urban hospital?' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 19:42:06
User closed query 'Per DM CLR: SAE Narrative = SINUS TACHYCARDIA . Review if this is to be recorded as a separate AE entry. Else, clarify. ' (Site from DM).		07 Apr 2021 11:26:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
Query 'Per DM CLR: SAE Narrative = SINUS TACHYCARDIA . Review if this is to be recorded as a separate AE entry. Else, clarify. ' answered with 'recorded as separate AE. thank you' (Site from DM).	Chelsie Nutsch (b) (4) (b) (4)	06 Apr 2021 13:39:51
User opened query 'Per DM CLR: SAE Narrative = SINUS TACHYCARDIA . Review if this is to be recorded as a separate AE entry. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 03:11:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ON 14MAR2021 THE SUBJECT WAS WALKING WHEN HE COLLAPSED AND HIT HIS HEAD. HE HAD A SEIZURE ACTIVITY. TRANSPORTED VIA EMS TO THE HOSPITAL. A CT SCAN REVEALED A BRAIN BLEED, WITH A LESION NOTED ON THAT LOCATION. HE WAS TRANSFERRED TO A LARGER URBAN HOSPITAL, WHERE HE UNDERWENT A BRIEF EVALUATION. HE WAS RELEASED THE SAME DAY AS EVENT. HE DID START ON ANTI SEIZURE MEDICATION. HE ALSO REPORTS HE MAY HAVE HAD AN EPISODE OF LOSING CONSCIOUS ABOUT A WEEK PRIOR TO THIS INCIDENT AS HE HAD A SIMILAR METAL TASTE IN HIS MOUTH WHEN HE AWoKE. UPDATE 23 MAR 2021: MEDICAL RECORDS RECEIVED AND REVIEWED. SUBJECT WAS IN A GAS STATION PARKING LOT AFTER CONTACT WITH THE POLICE. HE REPORTEDLY COLLAPSED AND EXPERIENCED APPROXIMATELY 30 SECONDS OF TONIC-CLONIC SEIZURE ACTIVITY. HE WAS TRANSFERRED TO THE ER VIA AMBULANCE. HE UNDERWENT BLOOD TESTING (NEGATIVE FOR ACUTE CHANGES) AND A CT OF HEAD WITHOUT CONTRAST. THE CT SHOWED A QUESTIONABLE 5 MM AREA OF MINERALIZATION. A 12 LEAD ECG AND TELEMETRY SHOWED SINUS TACHYCARDIA WITH RATES IN 110S CONSISTENT WITH DIAGNOSIS OF SEIZURE. THE SUBJECT WAS GIVEN A ONE TIME BOLUS OF KEPPRA AND NS. HE WAS TRANSFERRED TO A LARGE URBAN HOSPITAL FOR FURTHER EVALUATION. IT SHOULD BE NOTED ER REPORTS INDICATE SUBJECT HAS A HX OF SEIZURES, WHICH HAD NOT BEEN NOTED BY SUBJECT DURING PAST VISITS. UPDATE 31MAR2021: MEDICAL RECORDS FROM THE URBAN HOSPITAL ARE REVIEWED. CT of head overread	Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 19:44:27

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[Narrative](#)

Audit	User	Time (GMT)
by neurologists and is negative for acute or chronic changes. No bleeding or calcifications noted. Also, blood alcohol level was 74 at urban hospital, drug screen negative. CK elevated. will follow-up outpatient for EEG at epilepsy clinic.' reason for change: New Information		

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Generated On: 09 Jun 2021 14:55:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ON 14MAR2021 THE SUBJECT WAS WALKING WHEN HE COLLAPSED AND HIT HIS HEAD. HE HAD A SEIZURE ACTIVITY UNCONSCIOUS AND WAS TRANSPORTED VIA EMS TO THE HOSPITAL. A CAT SCAN REVEALED A BRAIN BLEED, WITH A LESION NOTED ON THAT LOCATION. HE WAS TRANSFERRED TO A LARGER URBAN HOSPITAL, WHERE HE UNDERWENT A BRIEF EVALUATION. HE WAS RELEASED THE SAME DAY AS EVENT. HE DID START ON ANTI SEIZURE MEDICATION, THOUGH HE DOES NOT HAVE THE PRESCRIPTION WITH HIM TODAY AT VISIT. HE HAD ANOTHER CAT SCAN ON 18MAR2021 THAT GAVE A PICTURE OF THE LESION. IT IS UNKNOWN IF THIS LESION IS CANCEROUS OR A MINERAL DEPOSIT. THE SUBJECT REPORTS HE HAS A STRONG FAMILY HISTORY OF CANCER. HE ALSO REPORTS HE MAY HAVE HAD AN EPISODE OF LOSING CONSCIOUS ABOUT A WEEK PRIOR TO THIS INCIDENT AS HE HAD A SIMILAR METAL TASTE IN HIS MOUTH WHEN HE AWAKE. AT PRESENT THE SUBJECT IS CONTINUING TO LIVE AS NORMAL. HE RETURNS TO WORK TODAY AND ONLY HAS A DRIVING RESTRICTION. MEDICAL RELEASE IS SIGNED FOR FOLLOW UP. UPDATE 23 MAR 2021: MEDICAL RECORDS RECEIVED AND REVIEWED. SUBJECT WAS IN A GAS STATION PARKING LOT AFTER CONTACT WITH THE POLICE. HE REPORTEDLY COLLAPSED AND EXPERIENCED APPROXIMATELY 30 SECONDS OF TONIC-CLONIC SEIZURE ACTIVITY. HE WAS TRANSFERRED TO THE ER VIA AMBULANCE. HE UNDERWENT BLOOD TESTING (NEGATIVE FOR ACUTE CHANGES) AND A CT OF HEAD WITHOUT CONTRAST. THE CT SHOWED A QUESTIONABLE 5 MM AREA OF MINERALIZATION. A 12 LEAD ECG	Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 19:32:06

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[Narrative](#)

Audit	User	Time (GMT)
AND TELEMETRY SHOWED SINUS TACHYCARDIA WITH RATES IN 110S CONSISTENT WITH DIAGNOSIS OF SEIZURE. THE SUBJECT WAS GIVEN A ONE TIME BOLUS OF KEPPRA AND NS. HE WAS TRANSFERRED TO A LARGE URBAN HOSPITAL FOR FURTHER EVALUATION. AWAITING THOSE MEDICAL RECORDS. IT SHOULD BE NOTED ER REPORTS INDICATE SUBJECT HAS A HX OF SEIZURES, WHICH HAD NOT BEEN NOTED BY SUBJECT DURING PAST VISITS. Update 31Mar2021: medical records from the urban hospital are reviewed. subject had been transferred to that hospital for further evaluation/treatment of seizure and possible brain bleed. The exam perform' reason for change: New Information		
User closed query 'PV Query: Please confirm if the subject had a history of seizures. If yes, then kindly add the same in the medical history section of the CRF. If No, then please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 14:42:55
User closed query 'PV Query: Did the subject undergo any additional treatment for brain bleed and brain lesion? If yes, kindly provide details of the same. If No, then please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 14:51:05
User closed query 'PV Query: As per the narrative the subject experienced an episode of loss of consciousness, one week prior. Kindly report the same as separate AE/SAE..' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 14:51:01
Query 'PV Query: As per the narrative the subject experienced an episode of loss of consciousness, one week prior. Kindly report the same as separate AE/SAE..' answered with 'updated' (Site from Safety).	Samantha Wieseler (b) (4)	26 Mar 2021 14:03:41
Query 'PV Query: Please confirm if the subject had a history of seizures. If yes, then kindly add the same in the medical history section of the CRF. If No, then please state so.' answered with 'updated' (Site from Safety).	Samantha Wieseler (b) (4)	26 Mar 2021 14:03:34

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ON 14MAR2021 THE SUBJECT WAS WALKING WHEN HE COLLAPSED AND HIT HIS HEAD. HE HAD A SEIZURE ACTIVITY UNCONSCIOUS AND WAS TRANSPORTED VIA EMS TO THE HOSPITAL. A CAT SCAN REVEALED A BRAIN BLEED, WITH A LESION NOTED ON THAT LOCATION. HE WAS TRANSFERRED TO A LARGER URBAN HOSPITAL, WHERE HE UNDERWENT A BRIEF EVALUATION. HE WAS RELEASED THE SAME DAY AS EVENT. HE DID START ON ANTI SEIZURE MEDICATION, THOUGH HE DOES NOT HAVE THE PRESCRIPTION WITH HIM TODAY AT VISIT. HE HAD ANOTHER CAT SCAN ON 18MAR2021 THAT GAVE A PICTURE OF THE LESION. IT IS UNKNOWN IF THIS LESION IS CANCEROUS OR A MINERAL DEPOSIT. THE SUBJECT REPORTS HE HAS A STRONG FAMILY HISTORY OF CANCER. HE ALSO REPORTS HE MAY HAVE HAD AN EPISODE OF LOSING CONSCIOUS ABOUT A WEEK PRIOR TO THIS INCIDENT AS HE HAD A SIMILAR METAL TASTE IN HIS MOUTH WHEN HE AWAKE. AT PRESENT THE SUBJECT IS CONTINUING TO LIVE AS NORMAL. HE RETURNS TO WORK TODAY AND ONLY HAS A DRIVING RESTRICTION. MEDICAL RELEASE IS SIGNED FOR FOLLOW UP. UPDATE 23 MAR 2021: MEDICAL RECORDS RECEIVED AND REVIEWED. SUBJECT WAS IN A GAS STATION PARKING LOT AFTER CONTACT WITH THE POLICE. HE REPORTEDLY COLLAPSED AND EXPERIENCED APPROXIMATELY 30 SECONDS OF TONIC-CLONIC SEIZURE ACTIVITY. HE WAS TRANSFERRED TO THE ER VIA AMBULANCE. HE UNDERWENT BLOOD TESTING (NEGATIVE FOR ACUTE CHANGES) AND A CT OF HEAD WITHOUT CONTRAST. THE CT SHOWED A QUESTIONABLE 5 MM AREA OF MINERALIZATION. A 12 LEAD ECG	Samantha Wieseler (b) (4) (b) (4)	(b) (4) 26 Mar 2021 14:03:17

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[Narrative](#)

Audit	User	Time (GMT)
AND TELEMETRY SHOWED SINUS TACHYCARDia WITH RATES IN 110S CONSISTENT WITH DIAGNOSIS OF SEIZURE. THE SUBJECT WAS GIVEN A ONE TIME BOLUS OF KEPPRA AND NS. HE WAS TRANSFERRED TO A LARGE URBAN HOSPITAL FOR FURTHER EVALUATION. AWAITING THOSE MEDICAL RECORDS. IT SHOULD BE NOTED ER REPORTS INDICATE SUBJECT HAS A HX OF SEIZURES, WHICH HAD NOT BEEN NOTED BY SUBJECT DURING PAST VISITS.' reason for change: New Information Query 'PV Query: Did the subject undergo any additional treatment for brain bleed and brain lesion? If yes, kindly provide details of the same. If No, then please state so.' answered with 'subject is planning on more testing. testing has not happened at this time. ' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	26 Mar 2021 13:43:40
User opened query 'PV Query: Did the subject undergo any additional treatment for brain bleed and brain lesion? If yes, kindly provide details of the same. If No, then please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 21:03:49
User opened query 'PV Query: Please confirm if the subject had a history of seizures. If yes, then kindly add the same in the medical history section of the CRF. If No, then please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 21:03:41
User opened query 'PV Query: As per the narrative the subject experienced an episode of loss of consciousness, one week prior. Kindly report the same as separate AE/SAE..' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 21:03:34

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'ON 14MAR2021 THE SUBJECT WAS WALKING WHEN HE COLLAPSED AND HIT HIS HEAD. HE HAD A SEIZURE ACTIVITY UNCONSCIOUS AND WAS TRANSPORTED VIA EMS TO THE HOSPITAL. A CAT SCAN REVEALED A BRAIN BLEED, WITH A LESION NOTED ON THAT LOCATION. HE WAS TRANSFERRED TO A LARGER URBAN HOSPITAL, WHERE HE UNDERWENT A BRIEF EVALUATION. HE WAS RELEASED THE SAME DAY AS EVENT. HE DID START ON ANTI SEIZURE MEDICATION, THOUGH HE DOES NOT HAVE THE PRESCRIPTION WITH HIM TODAY AT VISIT. HE HAD ANOTHER CAT SCAN ON 18MAR2021 THAT GAVE A PICTURE OF THE LESION. IT IS UNKNOWN IF THIS LESION IS CANCEROUS OR A MINERAL DEPOSIT. THE SUBJECT REPORTS HE HAS A STRONG FAMILY HISTORY OF CANCER. HE ALSO REPORTS HE MAY HAVE HAD AN EPISODE OF LOSING CONSCIOUS ABOUT A WEEK PRIOR TO THIS INCIDENT AS HE HAD A SIMILAR METAL TASTE IN HIS MOUTH WHEN HE AWAKE. AT PRESENT THE SUBJECT IS CONTINUING TO LIVE AS NORMAL. HE RETURNS TO WORK TODAY AND ONLY HAS A DRIVING RESTRICTION. MEDICAL RELEASE IS SIGNED FOR FOLLOW UP. Update 23 Mar 2021: medical records received and reviewed. Subject was in a gas station parking lot after contact with the police. he reportedly collapsed and experienced approximately 30 seconds of tonic-clonic seizure activity. he was transferred to the ER via ambulance. he underwent blood testing (negative for acute changes) and a CT of head without contrast. the CT showed a questionable 5 mm area of mineralization. a 12 lead ecg and telemetry showed sinus tachycard with rates in 110s consistent with diagnosis of seizure. the subject was given a one time bolus of keppra and NS. he was transferred to a large urban hospital for further evaluation. awaiting	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:11:59

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[Narrative](#)

Audit	User	Time (GMT)
those medical records. it should be noted ER reports indicate subject has a hx of seizures, which had not been noted by subject during past visits.' reason for change: New Information		
User entered 'On 14Mar2021 the subject was walking when he collapsed and hit his head. He had a seizure activity unconscious and was transported via EMS to the hospital. A CAT scan revealed a brain bleed, with a lesion noted on that location. He was transferred to a larger Urban hospital, where he underwent a brief evaluation. He was released the same day as event. He did start on anti seizure medication, though he does not have the prescription with him today at visit. He had another CAT scan on 18Mar2021 that gave a picture of the lesion. It is unknown if this lesion is cancerous or a mineral deposit. The subject reports he has a strong family history of cancer. He also reports he may have had an episode of losing conscious about a week prior to this incident as he had a similar metal taste in his mouth when he awake. At present the subject is continuing to live as normal. He returns to work today and only has a driving restriction. Medical release is signed for follow up.' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	18 Mar 2021 22:18:48
User entered 'SUBJECT FELL AND HAD A SEIZURE. WHEN SUBJECT WENT TO ER, A BRAIN BLOOD WAS FOUND. Awaiting medical records for further detail' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:01
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Mar 2021 22:06:38
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	18 Mar 2021 22:06:38
User entered 'Subject fell and had a seizure. When subject went to ER, a brain blood was found.' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	18 Mar 2021 22:06:38
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Mar 2021 22:05:09

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Samantha Wieseler (b) (4)	18 Mar 2021 22:03:52
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 22:05:09
User entered '0'	System	18 Mar 2021 22:03:52

US3032337

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 22:03:52

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Traumatic haemorrhage, LLT: Traumatic hemorrhage - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	24 Mar 2021 12:53:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 12:53:00
Data point term sent to Coder	System	18 Mar 2021 22:07:54
User entered 'traumatic hemorrhage of cerebrum, unspecified'	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:07:49

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'No (N)'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'No (N)'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '14 Mar 2021'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 22:07:49

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 22:07:49

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'No (N)'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:07:49

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:07:49

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '1'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	18 Mar 2021 22:07:49
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:07:49

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Mar 2021 22:07:49

US3032337

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 22:07:49

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 22:10:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 22:10:32
Data point term sent to Coder	System	18 Mar 2021 22:10:15
User entered 'Fall'	Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User entered empty.	System	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User entered empty.	System	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '1'	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Samantha Wieseler (b) (4) (b) (4)	18 Mar 2021 22:09:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

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 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	18 Mar 2021 22:09:19
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User entered '0'	System	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57
User entered '1'	System	18 Mar 2021 22:09:19

US3032337

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:57

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 22:45:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 22:45:42
Data point term sent to Coder	System	18 Mar 2021 22:44:59
User entered 'UPPER RESPIRATORY INFECTION'	Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

US3032337

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

US3032337

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '27 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User entered empty.	System	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '12 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User entered empty.	System	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

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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 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

US3032337

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	18 Mar 2021 22:45:08
User entered '1' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	18 Mar 2021 22:45:08
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	18 Mar 2021 22:44:58
User entered '0'	Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

US3032337

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

US3032337

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

US3032337

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

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 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User entered '0'	System	18 Mar 2021 22:44:58

US3032337

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23
User entered '0'	System	18 Mar 2021 22:44:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:23

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Loss of consciousness, LLT: Loss of consciousness - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 14:06:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 14:06:02
Data point term sent to Coder	System	26 Mar 2021 14:05:07
User entered 'loss of consciousness'	Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '05 Mar 2021'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User entered empty.	System	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '05 Mar 2021'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User entered empty.	System	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '1'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Mar 2021 14:04:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 14:04:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	26 Mar 2021 14:04:29
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Mar 2021 14:04:23
User entered empty.	System	26 Mar 2021 14:04:23
	Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

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 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User entered '0'	System	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28
User entered '0'	System	26 Mar 2021 14:04:23

US3032337

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:34

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:28

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User coded data point as SOC: Injury, poisoning and procedural complications, HLGTT: Exposures, chemical injuries and poisoning, HLT: Poisoning and toxicity, PT: Alcohol poisoning, LLT: Alcohol intoxication - version MedDRA\23.0.	Coder Import (b) (4)	05 Apr 2021 08:36:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	05 Apr 2021 08:36:57
Data point term sent to Coder	System	01 Apr 2021 19:20:56
User entered 'Alcohol intoxication without complication'	Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User entered empty.	System	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User entered empty.	System	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58
	(b) (4)	

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '1'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

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 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User entered '0'	System	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42
User entered '1'	System	01 Apr 2021 19:19:58

US3032337

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:55:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus tachycardia, LLT: Sinus tachycardia - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	06 Apr 2021 13:39:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:39:55
Data point term sent to Coder	System	06 Apr 2021 13:39:27
User entered 'Sinus Tachycardia'	Chelsie Nutsch (b) (4) (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User entered empty.	System	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User entered empty.	System	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '1'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

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 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User entered '0'	System	06 Apr 2021 13:39:22

US3032337

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49
User entered '1'	System	06 Apr 2021 13:39:22

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:55:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:49:49

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:55:34

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:12
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
Signature has been broken.	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:34:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:34:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:13:06

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Nov 2020 15:36:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Nov 2020 15:36:24
Data point term sent to Coder	System	04 Nov 2020 15:35:13
User entered 'Acetaminophen'	Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SLIGHT INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SLIGHT INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).		21 Dec 2020 17:36:59
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SLIGHT INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SLIGHT INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'SLIGHT INJECTION SITE PAIN did not meet the AE reporting criteria' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	15 Dec 2020 19:51:49

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SLIGHT INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SLIGHT INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	12 Dec 2020 13:38:52
	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered 'Slight Injection Site Pain'	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered '500'	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered 'mg (mg)'	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered 'as needed (PRN)'	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered 'Oral (ORAL)'	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered '22 Sep 2020'	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered '23 Sep 2020'	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:48
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User entered empty.	System	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User entered empty.	System	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:10
User entered empty.	System	04 Nov 2020 15:35:12

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Mar 2021 12:17:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 12:17:27
Data point term sent to Coder	System	23 Mar 2021 15:16:27
User entered 'levetiracetam'	Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'seizure'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '1000'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:16:20

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User entered empty.	System	23 Mar 2021 15:16:20

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User entered empty.	System	23 Mar 2021 15:16:20

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:17
User entered empty.	System	23 Mar 2021 15:16:20

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 13:49:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 13:49:51
Data point term sent to Coder Coding entries removed.	System Chelsie Nutsch (b) (4)	06 Apr 2021 13:41:33 06 Apr 2021 13:40:35
User entered 'SODIUM CHLORIDE 0.9%' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	06 Apr 2021 13:40:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Mar 2021 11:49:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Mar 2021 11:49:06
Data point term sent to Coder User entered 'sodium chloride'	System Kelsey Kelley (b) (4)	23 Mar 2021 15:17:28 23 Mar 2021 15:17:21

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:21
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'seizure'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:21

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User closed query 'Per DM CLR: Note, 0.9% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate. ' (Site from DM).		09 Apr 2021 11:49:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Query 'Per DM CLR: Note, 0.9% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate. ' answered with 'completed. thank you' (Site from DM).	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:40:45
User entered '1000' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	06 Apr 2021 13:40:35
User opened query 'Per DM CLR: Note, 0.9% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 12:58:11
User entered '0.9'	Kelsey Kelley (b) (4)	23 Mar 2021 15:17:21

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	06 Apr 2021 13:42:03
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	06 Apr 2021 13:40:35
User entered 'mL (mL)' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	06 Apr 2021 13:40:35
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:17:21

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty; reason for change Data Entry Error	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:42:03
User entered '%'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:21
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:21
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:21
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:21

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:21
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:21
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:21

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:21

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:21
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:21

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User entered empty.	System	23 Mar 2021 15:17:21

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User entered empty.	System	23 Mar 2021 15:17:21

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:40:24
User entered empty.	System	23 Mar 2021 15:17:21

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIPILEPTICS, ATC: ANTIPILEPTICS, ATC: OTHER ANTIPILEPTICS, PRODUCT: LEVETIRACETAM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 19:25:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Apr 2021 19:25:03
Data point term sent to Coder	System	01 Apr 2021 19:24:01
User entered 'Levetiracetam'	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'seizure'	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '1000'	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'twice daily (BID)'	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '14 Mar 2021'	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	01 Apr 2021 19:23:35
	(b) (4)	

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Apr 2021 19:23:35

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 19:23:35

US3032337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 19:23:35

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:55:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:12
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:39
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:17:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:20:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Aug 2020 18:18:04

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:55:34

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered '14 Mar 2021'	Kelsey Kelley (b) (4)	23 Mar 2021 15:18:11
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:55:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'electrocardiogram 12-lead'	Kelsey Kelley (b) (4)	23 Mar 2021 15:18:11
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:18:11
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:55:34

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:18:11
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:55:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:18:29
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:55:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'ct head without contrast'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:18:29

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:18:29
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:55:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:18:29
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:55:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:18:46
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:55:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'basal metabolic panel'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:18:46

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:18:46
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:55:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:18:46
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:55:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:19:06
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:55:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'complete blood count with differential'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:19:06
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:19:06
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:55:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:19:06
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:55:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:19:16
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:55:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'finger stick glucose'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:19:16

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:19:16
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:55:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:19:16
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:55:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:04
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:26:10
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:55:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:04
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'MRI brain with wo contrast'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 19:26:10

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:04
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:26:10
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:55:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:04
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:26:10
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:55:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:26:34
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:55:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'CT cervical spine WO contrast'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 19:26:34

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:26:34
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:55:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:26:34
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:55:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:26:45
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:55:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'chest x-ray'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:26:45

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:26:45
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:55:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:26:45
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:55:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:27:01
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:55:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'blood alcohol level'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:27:01
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:27:01
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:55:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:27:01
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:55:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:27:16
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:55:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'creatine kinase'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:27:16

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:27:16
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:55:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:27:16
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:55:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '14 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:27:36
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:55:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'drugs of abuse screen, urine'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:27:36
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:55:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:27:36
	(b) (4)	

US3032337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:55:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:00:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:27:36
	(b) (4)	

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u), (r), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'USA-US032-2021-MRNA-1273-P301000011'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u), (s), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u), (r), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Keith'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Vrbicky'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		29 Mar 2021 16:14:18
User entered 'US'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 17:22:57
User entered '5'	System	02 Apr 2021 13:01:43
User entered '4'	System	29 Mar 2021 16:14:39
User entered '3'	System	29 Mar 2021 14:51:30
User entered '2'	System	24 Mar 2021 13:17:29
User entered '1'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'USA-US032-2021-MRNA-1273-P301000011'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (U), (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (*), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Keith'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Vrbicky'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		29 Mar 2021 16:14:18
User entered 'US'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 17:22:57
User entered '5'	System	02 Apr 2021 13:01:43
User entered '4'	System	29 Mar 2021 16:14:39
User entered '3'	System	29 Mar 2021 14:51:30
User entered '2'	System	24 Mar 2021 13:17:29
User entered '1'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:55:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '19/Mar/2021 09:48'	(b) (4) System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:55:34

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.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		29 Mar 2021 16:14:18
User entered 'I'		19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'USA-US032-2021-MRNA-1273-P301000011'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (c) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u), (r), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (U), (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Keith'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (U) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Vrbicky'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		29 Mar 2021 16:14:18
User entered 'US'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 17:22:57
User entered '5'	System	02 Apr 2021 13:01:43
User entered '4'	System	29 Mar 2021 16:14:39
User entered '3'	System	29 Mar 2021 14:51:30
User entered '2'	System	24 Mar 2021 13:17:29
User entered '1'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:55:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '24/Mar/2021 06:17'	(b) (4) System	24 Mar 2021 13:17:29

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:55:34

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.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		29 Mar 2021 16:14:18
User entered 'I'		24 Mar 2021 13:17:29

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'USA-US032-2021-MRNA-1273-P301000011'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u), (r), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u), (s), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Keith'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Vrbicky'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (*), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		29 Mar 2021 16:14:18
User entered 'US'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 17:22:57
User entered '5'	System	02 Apr 2021 13:01:43
User entered '4'	System	29 Mar 2021 16:14:39
User entered '3'	System	29 Mar 2021 14:51:30
User entered '2'	System	24 Mar 2021 13:17:29
User entered '1'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:55:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '29/Mar/2021 10:51'	(b) (4) System	29 Mar 2021 14:51:30

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:55:34

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.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		29 Mar 2021 16:14:18
User entered 'I'		29 Mar 2021 14:51:30

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'USA-US032-2021-MRNA-1273-P301000011'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4)	29 Mar 2021 16:14:25
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (*), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (U), (S), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (U) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (*), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (U), (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Keith'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Vrbicky'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		29 Mar 2021 16:14:18
User entered 'US'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 17:22:57
User entered '5'	System	02 Apr 2021 13:01:43
User entered '4'	System	29 Mar 2021 16:14:39
User entered '3'	System	29 Mar 2021 14:51:30
User entered '2'	System	24 Mar 2021 13:17:29
User entered '1'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:55:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '29/Mar/2021 12:14'	(b) (4) System	29 Mar 2021 16:14:39

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:55:34

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.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:39

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'USA-US032-2021-MRNA-1273-P301000011'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u), (r), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (r), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (U) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Keith'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Vrbicky'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4)	29 Mar 2021 16:14:25
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:14:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:14:18
User entered 'US'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 17:22:57
User entered '5'	System	02 Apr 2021 13:01:43
User entered '4'	System	29 Mar 2021 16:14:39
User entered '3'	System	29 Mar 2021 14:51:30
User entered '2'	System	24 Mar 2021 13:17:29
User entered '1'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:55:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered '02/Apr/2021 06:01'	(b) (4) System	02 Apr 2021 13:01:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:55:34

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.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:01:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'USA-US032-2021-MRNA-1273-P301000011'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (v) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (U) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'No (N)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Yes (Y)'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (U) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Keith'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (u) (+), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		19 Mar 2021 16:48:25
User entered 'Vrbicky'	System	19 Mar 2021 16:47:59

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:14:25
Un-reviewed for Safety.		29 Mar 2021 16:14:22
Reviewed for Safety.		29 Mar 2021 16:14:18
User entered 'US'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 17:22:57
User entered '5'	System	02 Apr 2021 13:01:43
User entered '4'	System	29 Mar 2021 16:14:39
User entered '3'	System	29 Mar 2021 14:51:30
User entered '2'	System	24 Mar 2021 13:17:29
User entered '1'	System	19 Mar 2021 16:48:43

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:55:34

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:48
User entered '12/Apr/2021 10:22'	(b) (4) System	12 Apr 2021 17:22:57

US3032337

Folder: SAE USA-US032-2021-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:55:34

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.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:48
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:22:57