

US3742357 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:27:48

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US3742357

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:07:37

Generated On: 12 Aug 2021 13:27:48

Participant ID

US3742357

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

US3742357

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	53
Age Units	YEARS
Age (Derived)	53
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:47:42

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:47:42

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:47:42

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 25 Mar 2021 17:51:02

Generated On: 12 Aug 2021 13:27:48

Condition	GERD GASTRO ESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	15 MAR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Mar 2021 17:51:02

Generated On: 12 Aug 2021 13:27:48

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	DEC 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 25 Mar 2021 17:51:02

Generated On: 12 Aug 2021 13:27:48

Condition	BOTOX INJECTIONS
Start date (dd MMM yyyy)	UN JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	DEC 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:18 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 13:18
Height (<i>xxx.x</i>)	74.8 in
Weight (<i>xxx.x</i>)	235.8 lb
BMI (<i>xxx.x</i>)	29.69275 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:47:42

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:47:42

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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 True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:47:42

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:47:42

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What was the date of randomization? (dd MMM yyyy) 17 SEP 2020

What was the participant's randomization number? 114501

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) 15 Feb 2021 17:47:42

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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) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:55
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 14:21
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 13:47 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 13:47

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) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 SEP 2020

Collection time (00:00-23:59)

11:59 (24 HR)

Collection date and time (derived)

17 SEP 2020 11:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:01	17 SEP 2020 12:01
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

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: 12 Aug 2021 13:27:48

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 14:23

PC Open Date & Time

17 SEP 2020 14:07

PC Close Date & Time

17 SEP 2020 16:37

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	18 SEP 2020 07:25
PC Open Date & Time	17 SEP 2020 17:32
PC Close Date & Time	18 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 08:55

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

20 SEP 2020 09:39

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

21 SEP 2020 09:23

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 07:03

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

23 SEP 2020 09:40

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

24 SEP 2020 07:47

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 14:24

PC Open Date & Time

17 SEP 2020 14:07

PC Close Date & Time

17 SEP 2020 16:37

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

2

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

18 SEP 2020 07:30

PC Open Date & Time

17 SEP 2020 17:32

PC Close Date & Time

18 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 08:57

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 09:35

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 09:21

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 07:03

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 09:39

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 07:48

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 14:24
PC Open Date & Time	17 SEP 2020 14:07
PC Close Date & Time	17 SEP 2020 16:37

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 07:32
PC Open Date & Time	17 SEP 2020 17:32
PC Close Date & Time	18 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

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 ☒

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 08:56
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

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 ☒

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EAB) (1725)

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 09:34
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

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 ☒

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 09:21
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 07:03
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

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 ☒

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 09:39
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

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 ☒

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EAB) (1725)

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US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 07:48
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3742357

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742357

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742357

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742357

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742357

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:07:59

Generated On: 12 Aug 2021 13:27:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742357

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:07:59

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742357

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:47:43

Generated On: 12 Aug 2021 13:27:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:47:43

Generated On: 12 Aug 2021 13:27:48

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 12:00
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:47:43

Generated On: 12 Aug 2021 13:27:48

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	13:22 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 13:22
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3742357

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:47:43

Generated On: 12 Aug 2021 13:27:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3742357

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:47:43

Generated On: 12 Aug 2021 13:27:48

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) 15 OCT 2020

What was the treatment time? (00:00-23:59) 12:51 (24 HR)

Treatment Date and Time (derived) 15 OCT 2020 12:51

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

US3742357

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:47:43

Generated On: 12 Aug 2021 13:27:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

12:16 (24 HR)

Collection date and time (derived)

15 OCT 2020 12:16

US3742357

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:47:43

Generated On: 12 Aug 2021 13:27:48

Collection date (dd MMM yyyy)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:26	15 OCT 2020 12:26
Nasopharyngeal Swab 2	No		

US3742357

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:43

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

15 OCT 2020 13:28

PC Open Date & Time

15 OCT 2020 13:11

PC Close Date & Time

15 OCT 2020 15:41

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp	16 OCT 2020 00:08
PC Open Date & Time	15 OCT 2020 16:36
PC Close Date & Time	16 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 19:53

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 00:05

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

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

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 20:29

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 18:06

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 17:43

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

15 OCT 2020 13:29

PC Open Date & Time

15 OCT 2020 13:11

PC Close Date & Time

15 OCT 2020 15:41

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

2

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

16 OCT 2020 00:10

PC Open Date & Time

15 OCT 2020 16:36

PC Close Date & Time

16 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 19:53

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 00:05

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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.**

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 20:29

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 18:07

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 17:41

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 13:29
PC Open Date & Time	15 OCT 2020 13:11
PC Close Date & Time	15 OCT 2020 15:41

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 00:10
PC Open Date & Time	15 OCT 2020 16:36
PC Close Date & Time	16 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 19:55
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

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 ☒

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EAB) (1725)

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 00:05
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

Yes ☐

PC Time stamp

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 20:29
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

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 ☒

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 18:07
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

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 ☒

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 17:40
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3742357

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742357

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742357

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742357

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742357

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742357

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:42

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742357

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:47:43

Generated On: 12 Aug 2021 13:27:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:47:43

Generated On: 12 Aug 2021 13:27:48

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) _____

US3742357

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:47:43

Generated On: 12 Aug 2021 13:27:48

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.

US3742357

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:47:43

Generated On: 12 Aug 2021 13:27:48

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

Collection date (dd MMM yyyy)	16 NOV 2020
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Collection time (00:00-23:59)	13:25 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	16 NOV 2020 13:25
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US3742357

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:43

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742357

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 NOV 2020 17:15:45
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 10:19:06
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 06:50:20
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 10:19:51
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	16 DEC 2020 08:41:27
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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	19 DEC 2020 10:53:07
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	30 DEC 2020 09:36:18
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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	02 JAN 2021 19:05:14
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 22:11:53
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐ Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 JAN 2021 12:06:59
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	31 JAN 2021 18:43:33
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 12:20:32
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 FEB 2021 12:40:35
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	24 FEB 2021 07:56:35
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 10:11:27

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 12:05:04

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 18:15:53
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 08:37:32
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	31 MAR 2021 13:37:53
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

05 APR 2021 08:25:33

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

10 APR 2021 09:25:16

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 09:40:29

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 222

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 09:29:40

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 236

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

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

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

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

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

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

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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°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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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°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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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°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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

Patient Cloud Open Date & Time	13 NOV 2021 00:01
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Patient Cloud Close Date & Time	17 NOV 2021 23:59
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US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3742357

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:27:48

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
Yes	Yes	09 MAR 2021 12:04:47

US3742357

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:07:59

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:07:59

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742357

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742357

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:07:59

Generated On: 12 Aug 2021 13:27:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3742357

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742357

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:41:06

Generated On: 12 Aug 2021 13:27:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742357

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:41:06

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742357

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

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) _____

US3742357

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

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.

US3742357

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 APR 2021

Collection time (00:00-23:59)

12:54 (24 HR)

Collection date and time (derived)

22 APR 2021 12:54

US3742357

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742357

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

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 _____

US3742357

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

Date of Contact	08 DEC 2020
Time of Contact	10:10
Date and Time of Contact (derived)	08 DEC 2020 10:10
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99.7 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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"/>

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	97.4 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

	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"/>

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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"/>

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

	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"/>

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	92.6 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 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 08 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

	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 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 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 type="radio"/>
	Mild	<input checked="" 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 08 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

Date of Visit	08 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	08 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

Date of Contact	28 DEC 2020
Time of Contact	14:15
Date and Time of Contact (derived)	28 DEC 2020 14:15
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 ☐

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	25 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 ☐

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	26 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 ☐

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 ☐

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 ☐

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	False	
O2 Saturation	95 %	
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 type="radio"/>
	Mild	<input checked="" 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 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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

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Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	95 %	
O2 Saturation Units	%	
Temperature	96.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 21:48:34

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

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Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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

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Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	95 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 21:48:34

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

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Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 21:48:34

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

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Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	93 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (9)

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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 ☐

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Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	95 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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

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Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 ☐

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Form: Symptom Log (11)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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"/>

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Form: Symptom Log (11)

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	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	3 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (11)

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

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Form: Symptom Log (11)

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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 ☐

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Form: Symptom Log (12)

Data signed: (b) (4) 20 Apr 2021 21:48:34

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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"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	96 %	
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"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 20 Apr 2021 21:48:34

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

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Form: Symptom Log (12)

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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 ☐

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Form: Symptom Log (13)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	96 %	
O2 Saturation Units	%	
Temperature	96.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 20 Apr 2021 21:48:34

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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 ☐

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Form: Symptom Log (14)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	95 %	
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 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 type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (14)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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

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Form: Symptom Log (15)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	96 %	
O2 Saturation Units	%	
Temperature	97.9 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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Form: Symptom Log (15)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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"/>

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	95 %	
O2 Saturation Units	%	
Temperature	96.9 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 type="radio"/>
	Mild	<input checked="" 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 28 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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"/>

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 28 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 type="checkbox"/>
Day 18	<input checked="" 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 28 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	97 %	
O2 Saturation Units	%	
Temperature	97.6 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" 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 28 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

	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	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 20 Apr 2021 21:48:34

Generated On: 12 Aug 2021 13:27:48

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 ☐

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

Date of Visit	28 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	28 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 07 Apr 2021 21:41:06

Generated On: 12 Aug 2021 13:27:48

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date _____ 01 JAN 2021

End Date _____ 01 JAN 2021

Oxygen Saturation _____ 93 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 07 Apr 2021 21:41:06

Generated On: 12 Aug 2021 13:27:48

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 07 Apr 2021 21:41:06

Generated On: 12 Aug 2021 13:27:48

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3742357

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	10 DEC 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 DEC 2020
Day 5	Yes	01 JAN 2021
Day 7	Yes	03 JAN 2021
Day 9	Yes	05 JAN 2021
Day 14	Yes	10 JAN 2021
Day 21	Yes	17 JAN 2021
Day 28	Yes	03 FEB 2021

US3742357

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 DEC 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	08 DEC 2020 10:10
Height (xxx.x)	187.5 cm
Weight (xxx.x)	239.4 lb
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742357

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 DEC 2020

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

US3742357

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

08 DEC 2020

US3742357

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 DEC 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	28 DEC 2020 14:15
Height (xxx.x)	188.0 cm
Weight (xxx.x)	243.8 lb
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742357

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 DEC 2020

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

US3742357

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 DEC 2020

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 FEB 2021
Time of assessment (00:00-23:59)	13:06 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 13:06
Height (xxx.x)	187.8 cm
Weight (xxx.x)	241 lb
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 FEB 2021

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

US3742357

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

03 FEB 2021

US3742357

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

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

Visit date (dd MMM yyyy)	20 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3742357

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 21:48:23

Generated On: 12 Aug 2021 13:27:48

Date of updated informed consent (dd MMM yyyy) 20 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 20 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3742357

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 JAN 2021

Collection time (00:00-23:59)

09:00 (24 HR)

Collection date and time (derived)

20 JAN 2021 09:00

US3742357

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 JAN 2021

Collection time (00:00 - 23:59)

09:04

Collection Date and Time (derived)

20 JAN 2021 09:04

US3742357

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:07:37

Generated On: 12 Aug 2021 13:27:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

AEID

Adverse event

GENERALIZED BODY ACHES

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)

06 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

06 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

AEID

Adverse event

RIGHT MIDDLE FINER
LACERATION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

AEID

Adverse event

VIRAL ILLNESS 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)

05 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)

13 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

AEID	USA-US127-2021-MRNA-1273-P30 1000004
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	24 DEC 2020
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)	08 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

AEID	
Adverse event	CAT SCRATCH DISEASE
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)	03 APR 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)	09 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

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

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:07:38

Generated On: 12 Aug 2021 13:27:48

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

Yes ☒

No ☐

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

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

Name of Medication ZINC

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS SUPPLEMENT

Dose per administration 50

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) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS SUPPLEMENT

Dose per administration 1,000

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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US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

Name of Medication PAMTOPRAZOL

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED BODY ACHES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

	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)		06 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 06 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

Name of Medication CEPHALEXIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS INFECTION

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 (5)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

Name of Medication

NYQUIL LIQUID-
ACETAMINOPHEN 650 MG,
DEXTROMETHORPHAN 20 MG ,
DOXYLAMINE SUCCINATE 12.5
MG, PHENYLEPHRINE 10 MG

Prophylaxis

Yes ☐
No ☒

Indication

UNSPECIFIED VIRAL ILLNESS

Dose per administration

30

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 06 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

Name of Medication MENTHOL 10%, METHYL
SALICYLATE 30 %

Prophylaxis Yes ☐
No ☒

Indication VIRAL ILLNESS UNSPECIFIED

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	09 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication CAT SCRATCH DISEASE

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 (12)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication CAT SCRATCH DISEASE

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 17:55:39

Generated On: 12 Aug 2021 13:27:48

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	08 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742357

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 21:41:06

Generated On: 12 Aug 2021 13:27:48

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:27:48

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3742357

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:27:48

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 ☐

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

SAEID	USA-US127-2021-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

SAEID	USA-US127-2021-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	08/JAN/2021 12:37
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

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 18:07:40

Generated On: 12 Aug 2021 13:27:48

SAEID	USA-US127-2021-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	11/FEB/2021 15:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3742357 (Prod: University of Maryland School of Medicine)

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Form: Participant Creation

Generated On: 12 Aug 2021 13:27:48

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:30:10
User entered 'US3742357'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 16:45:02

US3742357

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:23
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:02

US3742357

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:23
User entered '14 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 16:45:04

US3742357

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:23
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:02

US3742357

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'SCRN'	System	15 Sep 2020 18:45:02

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:29
User entered (b) (6) 1967'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 16:45:05

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:29
User entered '53'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:22

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'YEARS'	System	15 Sep 2020 18:45:22

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered '53'	System	15 Sep 2020 18:45:40

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:29
User entered 'Male (M)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:22

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:29
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:22

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:29
User entered 'I'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:22

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:29
User entered '0'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:22

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:29
User entered '0'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:22

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:29
User entered '0'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:22

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:29
User entered '0'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:22

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:29
User entered '0'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:22

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:29
User entered empty.	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:22

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:29
User entered '0'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:22

US3742357

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:48

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:29
User entered '0'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:22

US3742357

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:48

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:37
User entered '14 Sep 2020'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:40

US3742357

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'Sep 2020'	System	15 Sep 2020 18:45:40

US3742357

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered '2020'	System	15 Sep 2020 18:45:40

US3742357

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:37
User entered 'Amendment 3 (3)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:40

US3742357

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:37
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:40

US3742357

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:48

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:37
User entered empty.	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:40

US3742357

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:37
User entered empty.	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:40

US3742357

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:37
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:45:40

US3742357

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:37
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 16:45:04

US3742357

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'I'	System	15 Sep 2020 18:46:17

US3742357

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:44
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:46:17

US3742357

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:27:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:14:49
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:24:56

US3742357

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:11
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 13:26:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 13:26:55
Data point term sent to Coder	System	18 Sep 2020 13:26:17
User entered 'GERD GASTRO ESOPHAGEAL REFLUX DISEASE'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:25:54

US3742357

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:11
User entered '15 Mar 2019'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:25:54

US3742357

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:11
User entered '0'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:25:54

US3742357

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:25:54

US3742357

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:11
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:25:54

US3742357

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:11
User entered '0'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:25:54

US3742357

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'Mar 2019'	System	18 Sep 2020 13:25:54

US3742357

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:48

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered '2019'	System	18 Sep 2020 13:25:54

US3742357

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered empty.	System	18 Sep 2020 13:25:54

US3742357

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered empty.	System	18 Sep 2020 13:25:54

US3742357

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:57:48
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:51:02
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Mar 2021 17:02:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:02:54
Data point term sent to Coder	System	16 Mar 2021 17:01:51
User entered 'migraines'	Sherry McCammon (b) (4) (b) (4)	16 Mar 2021 17:01:08

US3742357

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:57:48
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:51:02
User entered 'UN Jun 2019'	(b) (4) Sherry McCammon (b) (4) (b) (4)	16 Mar 2021 17:01:08

US3742357

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:57:48
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:51:02
User entered '0'	(b) (4) Sherry McCammon (b) (4) (b) (4)	16 Mar 2021 17:01:08

US3742357

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:57:48
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:51:02
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	
	System	16 Mar 2021 17:01:57
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	16 Mar 2021 17:01:08
User entered 'No (N)'	Sherry McCammon (b) (4)	16 Mar 2021 17:01:08
	(b) (4)	

US3742357

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:57:48
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:51:02
User entered 'UN Dec 2019' reason for change: Data Entry Error	(b) (4)	16 Mar 2021 17:01:57
User entered empty.	Sherry McCammon (b) (4)	16 Mar 2021 17:01:08
	(b) (4)	

US3742357

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:57:48
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:51:02
User entered '0'	(b) (4) Sherry McCammon (b) (4) (b) (4)	16 Mar 2021 17:01:08

US3742357

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:48

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'Jun 2019'	System	16 Mar 2021 17:01:08

US3742357

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:48

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered '2019'	System	16 Mar 2021 17:01:08

US3742357

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'Dec 2019'	System	16 Mar 2021 17:01:57
User entered empty.	System	16 Mar 2021 17:01:08

US3742357

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered '2019'	System	16 Mar 2021 17:01:57
User entered empty.	System	16 Mar 2021 17:01:08

US3742357

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:57:48
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:51:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 17:19:52
Data point term sent to Coder	(b) (4)	
User entered 'botox injections'	System	16 Mar 2021 17:03:53
	Sherry McCammon (b) (4)	16 Mar 2021 17:02:54
	(b) (4)	

US3742357

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:57:48
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:51:02
User entered 'UN Jun 2019'	(b) (4) Sherry McCammon (b) (4) (b) (4)	16 Mar 2021 17:02:54

US3742357

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:57:48
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:51:02
User entered '0'	(b) (4) Sherry McCammon (b) (4) (b) (4)	16 Mar 2021 17:02:54

US3742357

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:57:48
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:51:02
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	
	System	16 Mar 2021 17:03:07
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	16 Mar 2021 17:02:54
User entered 'No (N)'	Sherry McCammon (b) (4)	16 Mar 2021 17:02:54
	(b) (4)	

US3742357

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:57:48
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:51:02
User entered 'UN Dec 2019' reason for change: Data Entry Error	(b) (4)	(b) (4)
User entered empty.	Sherry McCammon (b) (4)	16 Mar 2021 17:03:07
	(b) (4)	16 Mar 2021 17:02:54

US3742357

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:57:48
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:51:02
User entered '0'	(b) (4) Sherry McCammon (b) (4) (b) (4)	16 Mar 2021 17:02:54

US3742357

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:48

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'Jun 2019'	System	16 Mar 2021 17:02:54

US3742357

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered '2019'	System	16 Mar 2021 17:02:54

US3742357

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'Dec 2019'	System	16 Mar 2021 17:03:07
User entered empty.	System	16 Mar 2021 17:02:54

US3742357

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered '2019'	System	16 Mar 2021 17:03:07
User entered empty.	System	16 Mar 2021 17:02:54

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:36
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:36
User entered '14 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:36
User entered '13:18'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered '14 Sep 2020 13:18'	System	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:36
User entered '74.8' in	Sherry McCammon (b) (4)	18 Sep 2020 13:29:14
DataPoint set to visible.	(b) (4) System	15 Sep 2020 18:46:17

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:36
User entered '235.8' lb	Sherry McCammon (b) (4)	18 Sep 2020 13:29:14
DataPoint set to visible.	(b) (4) System	15 Sep 2020 18:46:17

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered '29.69275'	System	18 Sep 2020 13:29:14
DataPoint set to visible.	System	15 Sep 2020 18:46:17

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'kg/m2'	System	18 Sep 2020 13:29:14
DataPoint set to visible.	System	15 Sep 2020 18:46:17

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
User closed query 'Per CDM: The subject was "not" screened, randomized and dosed at the same day. However, Vital Signs Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure at Screening were Not Done. Please update if data are available or clarify why these were Not Done. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:34:36
Query 'Per CDM: The subject was "not" screened, randomized and dosed at the same day. However, Vital Signs Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure at Screening were Not Done. Please update if data are available or clarify why these were Not Done. ' answered with 'Updated ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:20:56
User opened query 'Per CDM: The subject was "not" screened, randomized and dosed at the same day. However, Vital Signs Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure at Screening were Not Done. Please update if data are available or clarify why these were Not Done. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 09:29:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:42:02
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 18:17:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:15:36
User entered missing code ND - Not Done.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:02
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 18:17:18
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:15:36
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:02
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 18:17:20
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:15:36
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:02
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 18:17:21
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:15:36
User entered missing code ND - Not Done.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'bpm'	System	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:02
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 18:17:23
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:15:36
User entered missing code ND - Not Done.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'breaths/min'	System	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:02
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 18:17:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:15:36
User entered missing code ND - Not Done.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'mmHg'	System	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:02
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 18:17:26
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:15:36
User entered missing code ND - Not Done.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User entered 'mmHg'	System	18 Sep 2020 13:29:14

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30

US3742357

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30

US3742357

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:42
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:24:07

US3742357

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:42
User entered '14 Sep 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	18 Sep 2020 13:28:23
User entered '17 Sep 2020'	(b) (4) Sherry McCammon (b) (4)	18 Sep 2020 13:24:07

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

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)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

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)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

[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)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

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)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

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)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

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[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)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

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)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

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)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered empty.	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
User entered 'I'	(b) (4) Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered '0'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

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)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered '0'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

[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)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered '0'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

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)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered '0'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered '0'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:57:30
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:15:59
User entered empty.	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 18:48:54

US3742357

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:16:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 18:17:07

US3742357

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:16:14
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 18:17:07

US3742357

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:16:14
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Sep 2020 18:17:07

US3742357

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'VISIT1'	System	17 Sep 2020 18:17:07

US3742357

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:39
User entered '17 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:49:23

US3742357

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:48

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:39
User entered '114501'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:49:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:39
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:49:23

US3742357

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:48

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)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 18:17:52

US3742357

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:48

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)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 18:17:52

US3742357

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 18:17:52

US3742357

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:48

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 18:17:52

US3742357

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 18:17:52

US3742357

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:48

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:41:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 18:21:43
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:21:39
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 17:26:21
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:10:24
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:10:23

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:27:32
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 16:21:10
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '72.5' in	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:27:32
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 16:21:10
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '237.4' lb	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:27:32
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 16:21:10
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '72.5' in	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:27:32
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 16:21:10
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '237.4' lb	(b) (4), (b) (6)	17 Sep 2020 20:43:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '11:55'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered '17 Sep 2020 11:55'	System	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '98.2' F	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '65'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'bpm'	System	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '16'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'breaths/min'	System	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '122'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'mmHg'	System	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '78'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'mmHg'	System	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:27:32
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 16:21:10
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '72.5' in	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:27:32
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 16:21:10
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '237.4' lb	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '14:21'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered '17 Sep 2020 14:21'	System	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '97.9' F	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '58'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'bpm'	System	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '16'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'breaths/min'	System	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '123'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'mmHg'	System	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:50
User entered '79'	(b) (4), (b) (6)	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'mmHg'	System	17 Sep 2020 20:43:19

US3742357

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:44:18

US3742357

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:21:58
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:44:18

US3742357

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 18:17:38

US3742357

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:04
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:17:38

US3742357

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

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)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:04
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:17:38

US3742357

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 18:17:38

US3742357

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:04
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 18:17:38

US3742357

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:04
User entered '13:47'	(b) (4), (b) (6)	17 Sep 2020 18:17:38

US3742357

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered '17 Sep 2020 13:47'	System	17 Sep 2020 18:17:38

US3742357

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:04
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	17 Sep 2020 18:17:38

US3742357

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:22:04
User entered 'ONCE'	System	17 Sep 2020 18:17:38

US3742357

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 18:17:38

US3742357

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:46:26

US3742357

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:10
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:46:26

US3742357

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:10
User entered '11:59'	(b) (4), (b) (6)	17 Sep 2020 20:46:26

US3742357

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered '17 Sep 2020 11:59'	System	17 Sep 2020 20:46:26

US3742357

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:27:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:18
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:48:37

US3742357

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Sep 2020 20:48:37

US3742357

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:48:37

US3742357

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:18
User entered '12:01'	(b) (4), (b) (6)	17 Sep 2020 20:48:37

US3742357

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered '17 Sep 2020 12:01'	System	17 Sep 2020 20:48:37

US3742357

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Sep 2020 20:48:37

US3742357

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:18
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 20:48:37

US3742357

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:18
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:48:37

US3742357

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:48

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered empty.	System	17 Sep 2020 20:48:37

US3742357

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:48:43

US3742357

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'I'	System	17 Sep 2020 20:48:43

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:23:09', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '226c75b9-8363-4ca4-b242-4b77cbe0dbe0'	System	17 Sep 2020 18:23:32
User entered 'Yes (Y)'	System	17 Sep 2020 18:23:32

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:23:18', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '226c75b9-8363-4ca4-b242-4b77cbe0dbe0' User entered '97.9'	System	17 Sep 2020 18:23:32
	System	17 Sep 2020 18:23:32

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:23:23', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '226c75b9-8363-4ca4-b242-4b77cbe0dbe0'	System	17 Sep 2020 18:23:32
User entered 'No (N)'	System	17 Sep 2020 18:23:32

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:23:28', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '226c75b9-8363-4ca4-b242-4b77cbe0dbe0'	System	17 Sep 2020 18:23:32
User entered '17 Sep 2020 14:23'	System	17 Sep 2020 18:23:32

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Sep 2020 14:07'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Sep 2020 16:37'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:24:57', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f3ed50c8-c7a0-4ea2-9b28-1f67c30990cd'	System	18 Sep 2020 11:25:43
User entered 'Yes (Y)'	System	18 Sep 2020 11:25:43

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:25:28', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f3ed50c8-c7a0-4ea2-9b28-1f67c30990cd' User entered '98.6'	System	18 Sep 2020 11:25:43

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:25:33', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f3ed50c8-c7a0-4ea2-9b28-1f67c30990cd'	System	18 Sep 2020 11:25:43
User entered 'No (N)'	System	18 Sep 2020 11:25:43

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:25:38', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f3ed50c8-c7a0-4ea2-9b28-1f67c30990cd'	System	18 Sep 2020 11:25:43
User entered '18 Sep 2020 07:25'	System	18 Sep 2020 11:25:43

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Sep 2020 17:32'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 2'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:54:15', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f92d3247-6fdd-4a84-a285-7b04361dc5ae'	System	19 Sep 2020 12:55:43
User entered 'Yes (Y)'	System	19 Sep 2020 12:55:43

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:55:24', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f92d3247-6fdd-4a84-a285-7b04361dc5ae'	System	19 Sep 2020 12:55:43
User entered '97.6'	System	19 Sep 2020 12:55:43

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:55:30', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f92d3247-6fdd-4a84-a285-7b04361dc5ae'	System	19 Sep 2020 12:55:43
User entered 'No (N)'	System	19 Sep 2020 12:55:43

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:55:41', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f92d3247-6fdd-4a84-a285-7b04361dc5ae'	System	19 Sep 2020 12:55:43
User entered '19 Sep 2020 08:55'	System	19 Sep 2020 12:55:43

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 3'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:35:40', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '65be58f9-3072-4092-890c-6a50f358f4af'	System	20 Sep 2020 13:39:16
User entered 'Yes (Y)'	System	20 Sep 2020 13:39:16

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:38:49', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '65be58f9-3072-4092-890c-6a50f358f4af'	System	20 Sep 2020 13:39:16
User entered '97.6'	System	20 Sep 2020 13:39:16

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:39:09', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '65be58f9-3072-4092-890c-6a50f358f4af'	System	20 Sep 2020 13:39:16
User entered 'No (N)'	System	20 Sep 2020 13:39:16

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:39:14', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '65be58f9-3072-4092-890c-6a50f358f4af'	System	20 Sep 2020 13:39:16
User entered '20 Sep 2020 09:39'	System	20 Sep 2020 13:39:16

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 4'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:22:41', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9a03b762-8db2-4394-a785-956b0252511f'	System	21 Sep 2020 13:23:27
User entered 'Yes (Y)'	System	21 Sep 2020 13:23:27

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:23:05', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9a03b762-8db2-4394-a785-956b0252511f' User entered '97.4'	System	21 Sep 2020 13:23:27

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:23:13', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9a03b762-8db2-4394-a785-956b0252511f'	System	21 Sep 2020 13:23:27
User entered 'No (N)'	System	21 Sep 2020 13:23:27

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:23:26', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9a03b762-8db2-4394-a785-956b0252511f' User entered '21 Sep 2020 09:23'	System	21 Sep 2020 13:23:27

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 5'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:02:49', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'c533169f-77c0-43fa-aa49-2822f740f762'	System	22 Sep 2020 11:03:12
User entered 'Yes (Y)'	System	22 Sep 2020 11:03:12

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:02:59', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'c533169f-77c0-43fa-aa49-2822f740f762'	System	22 Sep 2020 11:03:12
User entered '97.7'	System	22 Sep 2020 11:03:12

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:07', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'c533169f-77c0-43fa-aa49-2822f740f762'	System	22 Sep 2020 11:03:12
User entered 'No (N)'	System	22 Sep 2020 11:03:12

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:11', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'c533169f-77c0-43fa-aa49-2822f740f762'	System	22 Sep 2020 11:03:12
User entered '22 Sep 2020 07:03'	System	22 Sep 2020 11:03:12

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 6'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:46', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '1bb8b5e0-47f9-4784-8c6e-8612e6dd0a27'	System	23 Sep 2020 13:40:07
User entered 'Yes (Y)'	System	23 Sep 2020 13:40:07

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:57', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '1bb8b5e0-47f9-4784-8c6e-8612e6dd0a27'	System	23 Sep 2020 13:40:07
User entered '97.6'	System	23 Sep 2020 13:40:07

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:40:01', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '1bb8b5e0-47f9-4784-8c6e-8612e6dd0a27'	System	23 Sep 2020 13:40:07
User entered 'No (N)'	System	23 Sep 2020 13:40:07

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:40:05', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '1bb8b5e0-47f9-4784-8c6e-8612e6dd0a27'	System	23 Sep 2020 13:40:07
User entered '23 Sep 2020 09:40'	System	23 Sep 2020 13:40:07

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 7'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:47:28', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9f8b6991-d06a-4212-88e1-f652033bab3c'	System	24 Sep 2020 11:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 11:47:54

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:47:38', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9f8b6991-d06a-4212-88e1-f652033bab3c'	System	24 Sep 2020 11:47:54
User entered '98.0'	System	24 Sep 2020 11:47:54

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:47:44', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9f8b6991-d06a-4212-88e1-f652033bab3c'	System	24 Sep 2020 11:47:54
User entered 'No (N)'	System	24 Sep 2020 11:47:54

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:47:49', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9f8b6991-d06a-4212-88e1-f652033bab3c'	System	24 Sep 2020 11:47:54
User entered '24 Sep 2020 07:47'	System	24 Sep 2020 11:47:54

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:23:37', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '7d14b092-69bf-4b53-a7bb-5ed2d5f88dad'	System	17 Sep 2020 18:24:09
User entered 'None (1)'	System	17 Sep 2020 18:24:09

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:23:45', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '7d14b092-69bf-4b53-a7bb-5ed2d5f88dad'	System	17 Sep 2020 18:24:09
User entered 'No (N)'	System	17 Sep 2020 18:24:09

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:23:54', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '7d14b092-69bf-4b53-a7bb-5ed2d5f88dad'	System	17 Sep 2020 18:24:09
User entered 'No (N)'	System	17 Sep 2020 18:24:09

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:24:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '7d14b092-69bf-4b53-a7bb-5ed2d5f88dad'	System	17 Sep 2020 18:24:09
User entered 'None (1)'	System	17 Sep 2020 18:24:09

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:24:05', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '7d14b092-69bf-4b53-a7bb-5ed2d5f88dad'	System	17 Sep 2020 18:24:09
User entered '17 Sep 2020 14:24'	System	17 Sep 2020 18:24:09

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Sep 2020 14:07'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Sep 2020 16:37'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:26:08', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b527e730-2e9c-4056-b525-c36a1f9e9242'	System	18 Sep 2020 11:30:06
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 11:30:06

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:26:14', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b527e730-2e9c-4056-b525-c36a1f9e9242'	System	18 Sep 2020 11:30:06
User entered 'No (N)'	System	18 Sep 2020 11:30:06

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:26:49', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b527e730-2e9c-4056-b525-c36a1f9e9242'	System	18 Sep 2020 11:30:06
User entered 'Yes (Y)'	System	18 Sep 2020 11:30:06

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:29:45', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b527e730-2e9c-4056-b525-c36a1f9e9242'	System	18 Sep 2020 11:30:06
User entered '2'	System	18 Sep 2020 11:30:06

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:29:53', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b527e730-2e9c-4056-b525-c36a1f9e9242'	System	18 Sep 2020 11:30:06
User entered 'None (1)'	System	18 Sep 2020 11:30:06

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:30:01', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b527e730-2e9c-4056-b525-c36a1f9e9242'	System	18 Sep 2020 11:30:06
User entered '18 Sep 2020 07:30'	System	18 Sep 2020 11:30:06

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Sep 2020 17:32'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 2'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:56:42', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '5b81eeb2-1dc2-425a-93da-74921ebfd848'	System	19 Sep 2020 12:57:11
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 12:57:11

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:56:50', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '5b81eeb2-1dc2-425a-93da-74921ebfd848'	System	19 Sep 2020 12:57:11
User entered 'No (N)'	System	19 Sep 2020 12:57:11

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:56:55', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '5b81eeb2-1dc2-425a-93da-74921ebfd848'	System	19 Sep 2020 12:57:11
User entered 'No (N)'	System	19 Sep 2020 12:57:11

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:57:02', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '5b81eeb2-1dc2-425a-93da-74921ebfd848'	System	19 Sep 2020 12:57:11
User entered 'None (1)'	System	19 Sep 2020 12:57:11

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:57:08', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '5b81eeb2-1dc2-425a-93da-74921ebfd848'	System	19 Sep 2020 12:57:11
User entered '19 Sep 2020 08:57'	System	19 Sep 2020 12:57:11

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 3'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:35:06', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '5287c924-e605-41bf-8b3b-87f76c2c2671'	System	20 Sep 2020 13:35:27
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 13:35:27

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:35:13', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '5287c924-e605-41bf-8b3b-87f76c2c2671'	System	20 Sep 2020 13:35:27
User entered 'No (N)'	System	20 Sep 2020 13:35:27

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:35:16', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '5287c924-e605-41bf-8b3b-87f76c2c2671'	System	20 Sep 2020 13:35:27
User entered 'No (N)'	System	20 Sep 2020 13:35:27

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:35:22', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '5287c924-e605-41bf-8b3b-87f76c2c2671'	System	20 Sep 2020 13:35:27
User entered 'None (1)'	System	20 Sep 2020 13:35:27

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:35:26', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '5287c924-e605-41bf-8b3b-87f76c2c2671' User entered '20 Sep 2020 09:35'	System	20 Sep 2020 13:35:27
	System	20 Sep 2020 13:35:27

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 4'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:21:25', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '96c597dd-4a59-403e-8228-14fcd9359448'	System	21 Sep 2020 13:21:48
User entered 'None (1)'	System	21 Sep 2020 13:21:48

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:21:29', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '96c597dd-4a59-403e-8228-14fcd9359448'	System	21 Sep 2020 13:21:48
User entered 'No (N)'	System	21 Sep 2020 13:21:48

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:21:32', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '96c597dd-4a59-403e-8228-14fcd9359448'	System	21 Sep 2020 13:21:48
User entered 'No (N)'	System	21 Sep 2020 13:21:48

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:21:41', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '96c597dd-4a59-403e-8228-14fcd9359448'	System	21 Sep 2020 13:21:48
User entered 'None (1)'	System	21 Sep 2020 13:21:48

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:21:47', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '96c597dd-4a59-403e-8228-14fcd9359448'	System	21 Sep 2020 13:21:48
User entered '21 Sep 2020 09:21'	System	21 Sep 2020 13:21:48

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 5'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:16', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '7820f989-0701-40ca-9f10-401372760262'	System	22 Sep 2020 11:03:30
User entered 'None (1)'	System	22 Sep 2020 11:03:30

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:20', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '7820f989-0701-40ca-9f10-401372760262'	System	22 Sep 2020 11:03:30
User entered 'No (N)'	System	22 Sep 2020 11:03:30

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:23', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '7820f989-0701-40ca-9f10-401372760262'	System	22 Sep 2020 11:03:30
User entered 'No (N)'	System	22 Sep 2020 11:03:30

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:26', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '7820f989-0701-40ca-9f10-401372760262'	System	22 Sep 2020 11:03:30
User entered 'None (1)'	System	22 Sep 2020 11:03:30

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:28', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '7820f989-0701-40ca-9f10-401372760262'	System	22 Sep 2020 11:03:30
User entered '22 Sep 2020 07:03'	System	22 Sep 2020 11:03:30

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 6'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:29', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'fb05007b-959b-491e-8245-33e9a1c48afb'	System	23 Sep 2020 13:39:43
User entered 'None (1)'	System	23 Sep 2020 13:39:43

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:32', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'fb05007b-959b-491e-8245-33e9a1c48afb'	System	23 Sep 2020 13:39:43
User entered 'No (N)'	System	23 Sep 2020 13:39:43

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:36', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'fb05007b-959b-491e-8245-33e9a1c48afb'	System	23 Sep 2020 13:39:43
User entered 'No (N)'	System	23 Sep 2020 13:39:43

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:38', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'fb05007b-959b-491e-8245-33e9a1c48afb'	System	23 Sep 2020 13:39:43
User entered 'None (1)'	System	23 Sep 2020 13:39:43

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:40', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'fb05007b-959b-491e-8245-33e9a1c48afb'	System	23 Sep 2020 13:39:43
User entered '23 Sep 2020 09:39'	System	23 Sep 2020 13:39:43

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 7'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:47:56', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'c5a894ca-fcbc-417b-823c-18738a21b4ce'	System	24 Sep 2020 11:48:15
User entered 'None (1)'	System	24 Sep 2020 11:48:15

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:47:59', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'c5a894ca-fcbc-417b-823c-18738a21b4ce'	System	24 Sep 2020 11:48:15
User entered 'No (N)'	System	24 Sep 2020 11:48:15

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:48:03', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'c5a894ca-fcbc-417b-823c-18738a21b4ce'	System	24 Sep 2020 11:48:15
User entered 'No (N)'	System	24 Sep 2020 11:48:15

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:48:09', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'c5a894ca-fcbc-417b-823c-18738a21b4ce'	System	24 Sep 2020 11:48:15
User entered 'None (1)'	System	24 Sep 2020 11:48:15

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:48:13', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'c5a894ca-fcbc-417b-823c-18738a21b4ce'	System	24 Sep 2020 11:48:15
User entered '24 Sep 2020 07:48'	System	24 Sep 2020 11:48:15

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:24:13', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '0692dee7-0734-4e8e-9f39-9a34b2f56e79'	System	17 Sep 2020 18:24:49
User entered 'None (0)'	System	17 Sep 2020 18:24:49

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:24:17', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '0692dee7-0734-4e8e-9f39-9a34b2f56e79'	System	17 Sep 2020 18:24:49
User entered 'None (0)'	System	17 Sep 2020 18:24:49

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:24:21', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '0692dee7-0734-4e8e-9f39-9a34b2f56e79'	System	17 Sep 2020 18:24:49
User entered 'None (0)'	System	17 Sep 2020 18:24:49

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:24:24', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '0692dee7-0734-4e8e-9f39-9a34b2f56e79'	System	17 Sep 2020 18:24:49
User entered 'None (0)'	System	17 Sep 2020 18:24:49

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:24:28', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '0692dee7-0734-4e8e-9f39-9a34b2f56e79'	System	17 Sep 2020 18:24:49
User entered 'None (0)'	System	17 Sep 2020 18:24:49

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:24:32', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '0692dee7-0734-4e8e-9f39-9a34b2f56e79'	System	17 Sep 2020 18:24:49
User entered 'None (0)'	System	17 Sep 2020 18:24:49

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:24:37', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '0692dee7-0734-4e8e-9f39-9a34b2f56e79'	System	17 Sep 2020 18:24:49
User entered 'No (N)'	System	17 Sep 2020 18:24:49

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-17T14:24:40', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '0692dee7-0734-4e8e-9f39-9a34b2f56e79'	System	17 Sep 2020 18:24:49
User entered '17 Sep 2020 14:24'	System	17 Sep 2020 18:24:49

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Sep 2020 14:07'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Sep 2020 16:37'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:30:12', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ac20939f-adbc-4f3c-99da-2e44e927483e'	System	18 Sep 2020 11:32:06
User entered 'None (0)'	System	18 Sep 2020 11:32:06

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:30:28', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ac20939f-adbc-4f3c-99da-2e44e927483e'	System	18 Sep 2020 11:32:06
User entered 'No interference with activity (1)'	System	18 Sep 2020 11:32:06

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:30:46', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ac20939f-adbc-4f3c-99da-2e44e927483e'	System	18 Sep 2020 11:32:06
User entered 'No interference with activity (1)'	System	18 Sep 2020 11:32:06

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:30:50', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ac20939f-adbc-4f3c-99da-2e44e927483e'	System	18 Sep 2020 11:32:06
User entered 'None (0)'	System	18 Sep 2020 11:32:06

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:30:57', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ac20939f-adbc-4f3c-99da-2e44e927483e'	System	18 Sep 2020 11:32:06
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	18 Sep 2020 11:32:06

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:31:51', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ac20939f-adbc-4f3c-99da-2e44e927483e'	System	18 Sep 2020 11:32:06
User entered 'None (0)'	System	18 Sep 2020 11:32:06

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:32:01', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ac20939f-adbc-4f3c-99da-2e44e927483e'	System	18 Sep 2020 11:32:06
User entered 'No (N)'	System	18 Sep 2020 11:32:06

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-18T07:32:04', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ac20939f-adbc-4f3c-99da-2e44e927483e' User entered '18 Sep 2020 07:32'	System	18 Sep 2020 11:32:06
	System	18 Sep 2020 11:32:06

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Sep 2020 17:32'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 2'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:55:48', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'cdfb9228-8eed-4920-a4f6-5f53264ec3fc' User entered 'None (0)'	System	19 Sep 2020 12:56:36
	System	19 Sep 2020 12:56:36

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:55:53', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'cdfb9228-8eed-4920-a4f6-5f53264ec3fc'	System	19 Sep 2020 12:56:36
User entered 'None (0)'	System	19 Sep 2020 12:56:36

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:55:56', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'cdfb9228-8eed-4920-a4f6-5f53264ec3fc'	System	19 Sep 2020 12:56:36
User entered 'None (0)'	System	19 Sep 2020 12:56:36

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:56:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'cdfb9228-8eed-4920-a4f6-5f53264ec3fc'	System	19 Sep 2020 12:56:36
User entered 'None (0)'	System	19 Sep 2020 12:56:36

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:56:08', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'cdfb9228-8eed-4920-a4f6-5f53264ec3fc'	System	19 Sep 2020 12:56:36
User entered 'None (0)'	System	19 Sep 2020 12:56:36

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:56:12', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'cdfb9228-8eed-4920-a4f6-5f53264ec3fc'	System	19 Sep 2020 12:56:36
User entered 'None (0)'	System	19 Sep 2020 12:56:36

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:56:23', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'cdfb9228-8eed-4920-a4f6-5f53264ec3fc'	System	19 Sep 2020 12:56:36
User entered 'No (N)'	System	19 Sep 2020 12:56:36

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-19T08:56:33', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'cdfb9228-8eed-4920-a4f6-5f53264ec3fc'	System	19 Sep 2020 12:56:36
User entered '19 Sep 2020 08:56'	System	19 Sep 2020 12:56:36

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 3'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:34:21', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '8c289a21-b5fb-4fed-b947-1bf424e593fd'	System	20 Sep 2020 13:34:58
User entered 'None (0)'	System	20 Sep 2020 13:34:58

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:34:25', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '8c289a21-b5fb-4fed-b947-1bf424e593fd'	System	20 Sep 2020 13:34:58
User entered 'None (0)'	System	20 Sep 2020 13:34:58

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:34:30', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '8c289a21-b5fb-4fed-b947-1bf424e593fd'	System	20 Sep 2020 13:34:58
User entered 'None (0)'	System	20 Sep 2020 13:34:58

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:34:36', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '8c289a21-b5fb-4fed-b947-1bf424e593fd'	System	20 Sep 2020 13:34:58
User entered 'None (0)'	System	20 Sep 2020 13:34:58

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:34:39', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '8c289a21-b5fb-4fed-b947-1bf424e593fd'	System	20 Sep 2020 13:34:58
User entered 'None (0)'	System	20 Sep 2020 13:34:58

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:34:49', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '8c289a21-b5fb-4fed-b947-1bf424e593fd'	System	20 Sep 2020 13:34:58
User entered 'None (0)'	System	20 Sep 2020 13:34:58

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:34:54', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '8c289a21-b5fb-4fed-b947-1bf424e593fd'	System	20 Sep 2020 13:34:58
User entered 'No (N)'	System	20 Sep 2020 13:34:58

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-20T09:34:57', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '8c289a21-b5fb-4fed-b947-1bf424e593fd'	System	20 Sep 2020 13:34:58
User entered '20 Sep 2020 09:34'	System	20 Sep 2020 13:34:58

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 4'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:20:39', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3272c034-81c5-4b5d-b0e9-ba511e0d0de8'	System	21 Sep 2020 13:21:16
User entered 'None (0)'	System	21 Sep 2020 13:21:16

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:20:44', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3272c034-81c5-4b5d-b0e9-ba511e0d0de8'	System	21 Sep 2020 13:21:16
User entered 'None (0)'	System	21 Sep 2020 13:21:16

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:20:48', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3272c034-81c5-4b5d-b0e9-ba511e0d0de8' User entered 'None (0)'	System	21 Sep 2020 13:21:16
	System	21 Sep 2020 13:21:16

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:20:52', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3272c034-81c5-4b5d-b0e9-ba511e0d0de8'	System	21 Sep 2020 13:21:16
User entered 'None (0)'	System	21 Sep 2020 13:21:16

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:21:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3272c034-81c5-4b5d-b0e9-ba511e0d0de8' User entered 'None (0)'	System	21 Sep 2020 13:21:16
	System	21 Sep 2020 13:21:16

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:21:03', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3272c034-81c5-4b5d-b0e9-ba511e0d0de8'	System	21 Sep 2020 13:21:16
User entered 'None (0)'	System	21 Sep 2020 13:21:16

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:21:09', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3272c034-81c5-4b5d-b0e9-ba511e0d0de8'	System	21 Sep 2020 13:21:16
User entered 'No (N)'	System	21 Sep 2020 13:21:16

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-21T09:21:13', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3272c034-81c5-4b5d-b0e9-ba511e0d0de8' User entered '21 Sep 2020 09:21'	System	21 Sep 2020 13:21:16
	System	21 Sep 2020 13:21:16

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 5'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:32', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '30645e63-0c90-4dd0-8a7b-a453587c130d' User entered 'None (0)'	System	22 Sep 2020 11:03:51
	System	22 Sep 2020 11:03:51

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:34', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '30645e63-0c90-4dd0-8a7b-a453587c130d' User entered 'None (0)'	System	22 Sep 2020 11:03:51
	System	22 Sep 2020 11:03:51

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:36', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '30645e63-0c90-4dd0-8a7b-a453587c130d' User entered 'None (0)'	System	22 Sep 2020 11:03:51
	System	22 Sep 2020 11:03:51

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:38', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '30645e63-0c90-4dd0-8a7b-a453587c130d' User entered 'None (0)'	System	22 Sep 2020 11:03:51
	System	22 Sep 2020 11:03:51

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:41', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '30645e63-0c90-4dd0-8a7b-a453587c130d' User entered 'None (0)'	System	22 Sep 2020 11:03:51
	System	22 Sep 2020 11:03:51

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:43', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '30645e63-0c90-4dd0-8a7b-a453587c130d' User entered 'None (0)'	System	22 Sep 2020 11:03:51
	System	22 Sep 2020 11:03:51

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:46', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '30645e63-0c90-4dd0-8a7b-a453587c130d'	System	22 Sep 2020 11:03:51
User entered 'No (N)'	System	22 Sep 2020 11:03:51

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-22T07:03:49', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '30645e63-0c90-4dd0-8a7b-a453587c130d' User entered '22 Sep 2020 07:03'	System	22 Sep 2020 11:03:51
	System	22 Sep 2020 11:03:51

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 6'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:07', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '700750b0-7a45-4be9-af5e-e1b26595f1f4'	System	23 Sep 2020 13:39:25
User entered 'None (0)'	System	23 Sep 2020 13:39:25

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:09', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '700750b0-7a45-4be9-af5e-e1b26595f1f4'	System	23 Sep 2020 13:39:25
User entered 'None (0)'	System	23 Sep 2020 13:39:25

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:11', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '700750b0-7a45-4be9-af5e-e1b26595f1f4'	System	23 Sep 2020 13:39:25
User entered 'None (0)'	System	23 Sep 2020 13:39:25

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:13', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '700750b0-7a45-4be9-af5e-e1b26595f1f4'	System	23 Sep 2020 13:39:25
User entered 'None (0)'	System	23 Sep 2020 13:39:25

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:15', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '700750b0-7a45-4be9-af5e-e1b26595f1f4'	System	23 Sep 2020 13:39:25
User entered 'None (0)'	System	23 Sep 2020 13:39:25

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:18', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '700750b0-7a45-4be9-af5e-e1b26595f1f4'	System	23 Sep 2020 13:39:25
User entered 'None (0)'	System	23 Sep 2020 13:39:25

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:21', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '700750b0-7a45-4be9-af5e-e1b26595f1f4'	System	23 Sep 2020 13:39:25
User entered 'No (N)'	System	23 Sep 2020 13:39:25

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-23T09:39:23', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '700750b0-7a45-4be9-af5e-e1b26595f1f4'	System	23 Sep 2020 13:39:25
User entered '23 Sep 2020 09:39'	System	23 Sep 2020 13:39:25

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 7'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:48:18', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '2ca388bd-ebd9-4b86-98cf-5a7a85e36923'	System	24 Sep 2020 11:48:41
User entered 'None (0)'	System	24 Sep 2020 11:48:41

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:48:20', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '2ca388bd-ebd9-4b86-98cf-5a7a85e36923'	System	24 Sep 2020 11:48:41
User entered 'None (0)'	System	24 Sep 2020 11:48:41

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:48:22', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '2ca388bd-ebd9-4b86-98cf-5a7a85e36923'	System	24 Sep 2020 11:48:41
User entered 'None (0)'	System	24 Sep 2020 11:48:41

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:48:25', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '2ca388bd-ebd9-4b86-98cf-5a7a85e36923'	System	24 Sep 2020 11:48:41
User entered 'None (0)'	System	24 Sep 2020 11:48:41

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:48:29', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '2ca388bd-ebd9-4b86-98cf-5a7a85e36923'	System	24 Sep 2020 11:48:41
User entered 'None (0)'	System	24 Sep 2020 11:48:41

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:48:32', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '2ca388bd-ebd9-4b86-98cf-5a7a85e36923'	System	24 Sep 2020 11:48:41
User entered 'None (0)'	System	24 Sep 2020 11:48:41

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:48:35', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '2ca388bd-ebd9-4b86-98cf-5a7a85e36923'	System	24 Sep 2020 11:48:41
User entered 'No (N)'	System	24 Sep 2020 11:48:41

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-09-24T07:48:39', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '2ca388bd-ebd9-4b86-98cf-5a7a85e36923'	System	24 Sep 2020 11:48:41
User entered '24 Sep 2020 07:48'	System	24 Sep 2020 11:48:41

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:17:38

US3742357

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:58
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 19:57:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 19:57:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	24 Sep 2020 19:57:33
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 16:13:16
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:13:16

US3742357

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:58
User entered '24 Sep 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	24 Sep 2020 19:57:33
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:13:16

US3742357

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:58
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	24 Sep 2020 19:57:33
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:13:16

US3742357

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:22:58
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:13:16

US3742357

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:23:05
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	24 Sep 2020 19:57:39

US3742357

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'I'	System	24 Sep 2020 19:57:39

US3742357

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:23:16
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 16:15:33

US3742357

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:23:16
User entered '1 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 16:15:33

US3742357

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:23:16
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 16:15:33

US3742357

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 16:15:33

US3742357

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:23:21
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 16:15:36

US3742357

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'I'	System	01 Oct 2020 16:15:36

US3742357

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:23:31
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:16:21

US3742357

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:23:31
User entered '10 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:16:21

US3742357

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:23:31
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:16:21

US3742357

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:23:31
User entered empty.	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:16:21

US3742357

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:23:37
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:17:27

US3742357

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'I'	System	12 Oct 2020 18:17:27

US3742357

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:43:29

US3742357

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:38
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 17:43:29

US3742357

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:38
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Oct 2020 17:43:29

US3742357

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'VISIT2'	System	15 Oct 2020 17:43:29

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '12:00'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered '15 Oct 2020 12:00'	System	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '97.9' F	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '62'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'bpm'	System	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '12'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'breaths/min'	System	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '113'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'mmHg'	System	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '71'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'mmHg'	System	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '13:22'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered '15 Oct 2020 13:22'	System	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '98.3' F	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '58'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'bpm'	System	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '13'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'breaths/min'	System	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '111'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'mmHg'	System	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:51
User entered '74'	(b) (4), (b) (6)	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'mmHg'	System	15 Oct 2020 17:45:08

US3742357

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:42:58

US3742357

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:24:57
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 17:42:58

US3742357

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:26:34

US3742357

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:04
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 17:26:34

US3742357

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

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)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:04
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 17:26:34

US3742357

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 17:26:34

US3742357

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:04
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 17:26:34

US3742357

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:04
User entered '12:51'	(b) (4), (b) (6)	15 Oct 2020 17:26:34

US3742357

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered '15 Oct 2020 12:51'	System	15 Oct 2020 17:26:34

US3742357

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:04
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	15 Oct 2020 17:26:34

US3742357

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:25:04
User entered 'ONCE'	System	15 Oct 2020 17:26:34

US3742357

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 17:26:34

US3742357

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:45:37

US3742357

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:18
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 17:45:37

US3742357

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:18
User entered '12:16'	(b) (4), (b) (6)	15 Oct 2020 17:45:37

US3742357

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered '15 Oct 2020 12:16'	System	15 Oct 2020 17:45:37

US3742357

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:27:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:24
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 17:45:49

US3742357

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	15 Oct 2020 17:45:49

US3742357

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:45:49

US3742357

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:24
User entered '12:26'	(b) (4), (b) (6)	15 Oct 2020 17:45:49

US3742357

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered '15 Oct 2020 12:26'	System	15 Oct 2020 17:45:49

US3742357

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	15 Oct 2020 17:45:49

US3742357

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:24
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 17:45:49

US3742357

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:24
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 17:45:49

US3742357

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered empty.	System	15 Oct 2020 17:45:49

US3742357

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:46:14

US3742357

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'I'	System	15 Oct 2020 17:46:14

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:28:05', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'caa0d56d-ed22-4211-a22f-1c6dc2849674'	System	15 Oct 2020 17:28:31
User entered 'Yes (Y)'	System	15 Oct 2020 17:28:31

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:28:19', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'caa0d56d-ed22-4211-a22f-1c6dc2849674'	System	15 Oct 2020 17:28:31
User entered '98.3'	System	15 Oct 2020 17:28:31

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:28:24', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'caa0d56d-ed22-4211-a22f-1c6dc2849674'	System	15 Oct 2020 17:28:31
User entered 'No (N)'	System	15 Oct 2020 17:28:31

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:28:28', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'caa0d56d-ed22-4211-a22f-1c6dc2849674'	System	15 Oct 2020 17:28:31
User entered '15 Oct 2020 13:28'	System	15 Oct 2020 17:28:31

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '15 Oct 2020 13:11'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '15 Oct 2020 15:41'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:08:22', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '60384526-0cef-4deb-9931-675c2bb7c005'	System	16 Oct 2020 04:08:41
User entered 'Yes (Y)'	System	16 Oct 2020 04:08:41

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:08:28', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '60384526-0cef-4deb-9931-675c2bb7c005'	System	16 Oct 2020 04:08:41
User entered '97.7'	System	16 Oct 2020 04:08:41

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:08:33', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '60384526-0cef-4deb-9931-675c2bb7c005'	System	16 Oct 2020 04:08:41
User entered 'No (N)'	System	16 Oct 2020 04:08:41

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:08:39', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '60384526-0cef-4deb-9931-675c2bb7c005'	System	16 Oct 2020 04:08:41
User entered '16 Oct 2020 00:08'	System	16 Oct 2020 04:08:41

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '15 Oct 2020 16:36'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 2'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:52:14', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'cf69c6bc-da3c-4413-8563-d8ef361e7058'	System	16 Oct 2020 23:53:10
User entered 'Yes (Y)'	System	16 Oct 2020 23:53:10

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:52:21', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'cf69c6bc-da3c-4413-8563-d8ef361e7058'	System	16 Oct 2020 23:53:10
User entered '97.7'	System	16 Oct 2020 23:53:10

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:53:06', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'cf69c6bc-da3c-4413-8563-d8ef361e7058'	System	16 Oct 2020 23:53:10
User entered 'No (N)'	System	16 Oct 2020 23:53:10

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:53:09', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'cf69c6bc-da3c-4413-8563-d8ef361e7058'	System	16 Oct 2020 23:53:10
User entered '16 Oct 2020 19:53'	System	16 Oct 2020 23:53:10

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 3'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:00:34', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'a6336f16-04a4-485b-a0f7-89e2b30da27f'	System	18 Oct 2020 04:05:25
User entered 'Yes (Y)'	System	18 Oct 2020 04:05:25

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:14', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'a6336f16-04a4-485b-a0f7-89e2b30da27f'	System	18 Oct 2020 04:05:25
User entered '97.9'	System	18 Oct 2020 04:05:25

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:18', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'a6336f16-04a4-485b-a0f7-89e2b30da27f'	System	18 Oct 2020 04:05:25
User entered 'No (N)'	System	18 Oct 2020 04:05:25

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:21', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'a6336f16-04a4-485b-a0f7-89e2b30da27f'	System	18 Oct 2020 04:05:25
User entered '18 Oct 2020 00:05'	System	18 Oct 2020 04:05:25

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 4'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 5'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:28:41', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9d8637ab-2c78-499a-8c4f-c1106303320a'	System	20 Oct 2020 00:29:09
User entered 'Yes (Y)'	System	20 Oct 2020 00:29:09

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:28:50', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9d8637ab-2c78-499a-8c4f-c1106303320a' User entered '97.1'	System	20 Oct 2020 00:29:09

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:28:57', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9d8637ab-2c78-499a-8c4f-c1106303320a'	System	20 Oct 2020 00:29:09
User entered 'No (N)'	System	20 Oct 2020 00:29:09

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:01', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9d8637ab-2c78-499a-8c4f-c1106303320a'	System	20 Oct 2020 00:29:09
User entered '19 Oct 2020 20:29'	System	20 Oct 2020 00:29:09

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 6'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:05:04', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'fa4356b3-c712-416d-bd12-f10a7972f943'	System	20 Oct 2020 22:06:48
User entered 'Yes (Y)'	System	20 Oct 2020 22:06:48

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:05:14', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'fa4356b3-c712-416d-bd12-f10a7972f943'	System	20 Oct 2020 22:06:48
User entered '97.8'	System	20 Oct 2020 22:06:48

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:05:59', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'fa4356b3-c712-416d-bd12-f10a7972f943'	System	20 Oct 2020 22:06:48
User entered 'No (N)'	System	20 Oct 2020 22:06:48

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:06:43', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'fa4356b3-c712-416d-bd12-f10a7972f943'	System	20 Oct 2020 22:06:48
User entered '20 Oct 2020 18:06'	System	20 Oct 2020 22:06:48

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 7'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:41:17', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b7779f9b-6f9b-4c88-8212-5da3bc7d9680'	System	21 Oct 2020 21:43:35
User entered 'Yes (Y)'	System	21 Oct 2020 21:43:35

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:43:18', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b7779f9b-6f9b-4c88-8212-5da3bc7d9680'	System	21 Oct 2020 21:43:35
User entered '97.9'	System	21 Oct 2020 21:43:35

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:43:28', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b7779f9b-6f9b-4c88-8212-5da3bc7d9680'	System	21 Oct 2020 21:43:35
User entered 'No (N)'	System	21 Oct 2020 21:43:35

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:43:32', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b7779f9b-6f9b-4c88-8212-5da3bc7d9680'	System	21 Oct 2020 21:43:35
User entered '21 Oct 2020 17:43'	System	21 Oct 2020 21:43:35

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:28:36', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f7e47e74-d7cb-4c8f-bbb0-f0a3e433d6b9'	System	15 Oct 2020 17:29:13
User entered 'None (1)'	System	15 Oct 2020 17:29:13

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:28:55', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f7e47e74-d7cb-4c8f-bbb0-f0a3e433d6b9'	System	15 Oct 2020 17:29:13
User entered 'No (N)'	System	15 Oct 2020 17:29:13

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:28:59', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f7e47e74-d7cb-4c8f-bbb0-f0a3e433d6b9'	System	15 Oct 2020 17:29:13
User entered 'No (N)'	System	15 Oct 2020 17:29:13

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:29:08', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f7e47e74-d7cb-4c8f-bbb0-f0a3e433d6b9'	System	15 Oct 2020 17:29:13
User entered 'None (1)'	System	15 Oct 2020 17:29:13

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:29:11', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f7e47e74-d7cb-4c8f-bbb0-f0a3e433d6b9'	System	15 Oct 2020 17:29:13
User entered '15 Oct 2020 13:29'	System	15 Oct 2020 17:29:13

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '15 Oct 2020 13:11'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '15 Oct 2020 15:41'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:08:47', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3396b26d-f5ff-48cd-a18c-a9cc5f3fbe84'	System	16 Oct 2020 04:10:03
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 04:10:03

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:08:51', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3396b26d-f5ff-48cd-a18c-a9cc5f3fbe84'	System	16 Oct 2020 04:10:03
User entered 'No (N)'	System	16 Oct 2020 04:10:03

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:08:57', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3396b26d-f5ff-48cd-a18c-a9cc5f3fbe84'	System	16 Oct 2020 04:10:03
User entered 'Yes (Y)'	System	16 Oct 2020 04:10:03

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:09:37', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3396b26d-f5ff-48cd-a18c-a9cc5f3fbe84'	System	16 Oct 2020 04:10:03
User entered '2'	System	16 Oct 2020 04:10:03

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:09:49', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3396b26d-f5ff-48cd-a18c-a9cc5f3fbe84'	System	16 Oct 2020 04:10:03
User entered 'None (1)'	System	16 Oct 2020 04:10:03

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:10:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3396b26d-f5ff-48cd-a18c-a9cc5f3fbe84'	System	16 Oct 2020 04:10:03
User entered '16 Oct 2020 00:10'	System	16 Oct 2020 04:10:03

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '15 Oct 2020 16:36'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 2'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:53:17', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e1bd5874-82cd-4782-8f6a-e030123d6f60'	System	16 Oct 2020 23:53:46
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 23:53:46

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:53:22', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e1bd5874-82cd-4782-8f6a-e030123d6f60'	System	16 Oct 2020 23:53:46
User entered 'No (N)'	System	16 Oct 2020 23:53:46

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:53:31', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e1bd5874-82cd-4782-8f6a-e030123d6f60'	System	16 Oct 2020 23:53:46
User entered 'No (N)'	System	16 Oct 2020 23:53:46

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:53:43', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e1bd5874-82cd-4782-8f6a-e030123d6f60'	System	16 Oct 2020 23:53:46
User entered 'None (1)'	System	16 Oct 2020 23:53:46

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:53:46', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e1bd5874-82cd-4782-8f6a-e030123d6f60'	System	16 Oct 2020 23:53:46
User entered '16 Oct 2020 19:53'	System	16 Oct 2020 23:53:46

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 3'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:24', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '706024df-b314-493c-a6d0-8e33e80eac0d'	System	18 Oct 2020 04:05:41
User entered 'None (1)'	System	18 Oct 2020 04:05:41

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:29', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '706024df-b314-493c-a6d0-8e33e80eac0d'	System	18 Oct 2020 04:05:41
User entered 'No (N)'	System	18 Oct 2020 04:05:41

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:32', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '706024df-b314-493c-a6d0-8e33e80eac0d'	System	18 Oct 2020 04:05:41
User entered 'No (N)'	System	18 Oct 2020 04:05:41

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:35', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '706024df-b314-493c-a6d0-8e33e80eac0d'	System	18 Oct 2020 04:05:41
User entered 'None (1)'	System	18 Oct 2020 04:05:41

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:38', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '706024df-b314-493c-a6d0-8e33e80eac0d'	System	18 Oct 2020 04:05:41
User entered '18 Oct 2020 00:05'	System	18 Oct 2020 04:05:41

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 4'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

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)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

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)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 5'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:07', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '646d3ece-adde-4482-afd6-8c7e976f8b35'	System	20 Oct 2020 00:29:22
User entered 'None (1)'	System	20 Oct 2020 00:29:22

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:10', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '646d3ece-adde-4482-afd6-8c7e976f8b35'	System	20 Oct 2020 00:29:22
User entered 'No (N)'	System	20 Oct 2020 00:29:22

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:13', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '646d3ece-adde-4482-afd6-8c7e976f8b35'	System	20 Oct 2020 00:29:22
User entered 'No (N)'	System	20 Oct 2020 00:29:22

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:15', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '646d3ece-adde-4482-afd6-8c7e976f8b35'	System	20 Oct 2020 00:29:22
User entered 'None (1)'	System	20 Oct 2020 00:29:22

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:18', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '646d3ece-adde-4482-afd6-8c7e976f8b35'	System	20 Oct 2020 00:29:22
User entered '19 Oct 2020 20:29'	System	20 Oct 2020 00:29:22

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 6'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:06:51', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9620e72c-36bf-47ea-a80f-f0085b38a62f'	System	20 Oct 2020 22:07:19
User entered 'None (1)'	System	20 Oct 2020 22:07:19

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:06:57', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9620e72c-36bf-47ea-a80f-f0085b38a62f'	System	20 Oct 2020 22:07:19
User entered 'No (N)'	System	20 Oct 2020 22:07:19

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:07:06', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9620e72c-36bf-47ea-a80f-f0085b38a62f'	System	20 Oct 2020 22:07:19
User entered 'No (N)'	System	20 Oct 2020 22:07:19

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:07:14', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9620e72c-36bf-47ea-a80f-f0085b38a62f'	System	20 Oct 2020 22:07:19
User entered 'None (1)'	System	20 Oct 2020 22:07:19

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:07:17', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '9620e72c-36bf-47ea-a80f-f0085b38a62f' User entered '20 Oct 2020 18:07'	System	20 Oct 2020 22:07:19
	System	20 Oct 2020 22:07:19

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 7'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:40:57', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '47cd98c0-f8f7-4a63-914d-daf9e5745448'	System	21 Oct 2020 21:42:13
User entered 'None (1)'	System	21 Oct 2020 21:42:13

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:41:02', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '47cd98c0-f8f7-4a63-914d-daf9e5745448'	System	21 Oct 2020 21:42:13
User entered 'No (N)'	System	21 Oct 2020 21:42:13

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:41:04', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '47cd98c0-f8f7-4a63-914d-daf9e5745448'	System	21 Oct 2020 21:42:13
User entered 'No (N)'	System	21 Oct 2020 21:42:13

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:41:07', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '47cd98c0-f8f7-4a63-914d-daf9e5745448'	System	21 Oct 2020 21:42:13
User entered 'None (1)'	System	21 Oct 2020 21:42:13

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:41:10', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '47cd98c0-f8f7-4a63-914d-daf9e5745448'	System	21 Oct 2020 21:42:13
User entered '21 Oct 2020 17:41'	System	21 Oct 2020 21:42:13

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:29:17', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b4a119fb-22bc-4ae8-a124-90d3e352cbc2'	System	15 Oct 2020 17:29:41
User entered 'None (0)'	System	15 Oct 2020 17:29:41

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:29:22', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b4a119fb-22bc-4ae8-a124-90d3e352cbc2'	System	15 Oct 2020 17:29:41
User entered 'None (0)'	System	15 Oct 2020 17:29:41

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:29:25', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b4a119fb-22bc-4ae8-a124-90d3e352cbc2'	System	15 Oct 2020 17:29:41
User entered 'None (0)'	System	15 Oct 2020 17:29:41

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:29:28', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b4a119fb-22bc-4ae8-a124-90d3e352cbc2'	System	15 Oct 2020 17:29:41
User entered 'None (0)'	System	15 Oct 2020 17:29:41

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:29:30', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b4a119fb-22bc-4ae8-a124-90d3e352cbc2'	System	15 Oct 2020 17:29:41
User entered 'None (0)'	System	15 Oct 2020 17:29:41

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:29:33', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b4a119fb-22bc-4ae8-a124-90d3e352cbc2'	System	15 Oct 2020 17:29:41
User entered 'None (0)'	System	15 Oct 2020 17:29:41

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:29:37', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b4a119fb-22bc-4ae8-a124-90d3e352cbc2'	System	15 Oct 2020 17:29:41
User entered 'No (N)'	System	15 Oct 2020 17:29:41

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-15T13:29:40', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'b4a119fb-22bc-4ae8-a124-90d3e352cbc2'	System	15 Oct 2020 17:29:41
User entered '15 Oct 2020 13:29'	System	15 Oct 2020 17:29:41

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '15 Oct 2020 13:11'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '15 Oct 2020 15:41'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:10:09', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '33e27024-af3f-4d86-89f3-06bc0dbe6235'	System	16 Oct 2020 04:10:37
User entered 'No interference with activity (1)'	System	16 Oct 2020 04:10:37

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:10:13', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '33e27024-af3f-4d86-89f3-06bc0dbe6235'	System	16 Oct 2020 04:10:37
User entered 'None (0)'	System	16 Oct 2020 04:10:37

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:10:18', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '33e27024-af3f-4d86-89f3-06bc0dbe6235'	System	16 Oct 2020 04:10:37
User entered 'None (0)'	System	16 Oct 2020 04:10:37

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:10:22', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '33e27024-af3f-4d86-89f3-06bc0dbe6235'	System	16 Oct 2020 04:10:37
User entered 'None (0)'	System	16 Oct 2020 04:10:37

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:10:25', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '33e27024-af3f-4d86-89f3-06bc0dbe6235'	System	16 Oct 2020 04:10:37
User entered 'None (0)'	System	16 Oct 2020 04:10:37

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:10:28', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '33e27024-af3f-4d86-89f3-06bc0dbe6235'	System	16 Oct 2020 04:10:37
User entered 'None (0)'	System	16 Oct 2020 04:10:37

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:10:31', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '33e27024-af3f-4d86-89f3-06bc0dbe6235'	System	16 Oct 2020 04:10:37
User entered 'No (N)'	System	16 Oct 2020 04:10:37

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T00:10:33', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '33e27024-af3f-4d86-89f3-06bc0dbe6235' User entered '16 Oct 2020 00:10'	System	16 Oct 2020 04:10:37
	System	16 Oct 2020 04:10:37

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '15 Oct 2020 16:36'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 2'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:54:04', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '444a1608-267b-4c45-8df7-740e641077bd'	System	16 Oct 2020 23:55:18
User entered 'No interference with activity (1)'	System	16 Oct 2020 23:55:18

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:54:08', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '444a1608-267b-4c45-8df7-740e641077bd'	System	16 Oct 2020 23:55:18
User entered 'None (0)'	System	16 Oct 2020 23:55:18

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:54:29', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '444a1608-267b-4c45-8df7-740e641077bd'	System	16 Oct 2020 23:55:18
User entered 'No interference with activity (1)'	System	16 Oct 2020 23:55:18

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:54:34', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '444a1608-267b-4c45-8df7-740e641077bd'	System	16 Oct 2020 23:55:18
User entered 'No interference with activity (1)'	System	16 Oct 2020 23:55:18

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:54:40', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '444a1608-267b-4c45-8df7-740e641077bd' User entered 'None (0)'	System	16 Oct 2020 23:55:18
	System	16 Oct 2020 23:55:18

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:54:46', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '444a1608-267b-4c45-8df7-740e641077bd'	System	16 Oct 2020 23:55:18
User entered 'No interference with activity (1)'	System	16 Oct 2020 23:55:18

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:55:09', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '444a1608-267b-4c45-8df7-740e641077bd'	System	16 Oct 2020 23:55:18
User entered 'No (N)'	System	16 Oct 2020 23:55:18

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-16T19:55:14', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '444a1608-267b-4c45-8df7-740e641077bd' User entered '16 Oct 2020 19:55'	System	16 Oct 2020 23:55:18
	System	16 Oct 2020 23:55:18

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 3'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:42', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '72ffbb6a-0cb7-4981-8ad2-b942370555bc'	System	18 Oct 2020 04:06:00
User entered 'None (0)'	System	18 Oct 2020 04:06:00

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:43', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '72ffbb6a-0cb7-4981-8ad2-b942370555bc'	System	18 Oct 2020 04:06:00
User entered 'None (0)'	System	18 Oct 2020 04:06:00

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:45', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '72ffbb6a-0cb7-4981-8ad2-b942370555bc'	System	18 Oct 2020 04:06:00
User entered 'None (0)'	System	18 Oct 2020 04:06:00

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:46', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '72ffbb6a-0cb7-4981-8ad2-b942370555bc'	System	18 Oct 2020 04:06:00
User entered 'None (0)'	System	18 Oct 2020 04:06:00

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:47', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '72ffbb6a-0cb7-4981-8ad2-b942370555bc'	System	18 Oct 2020 04:06:00
User entered 'None (0)'	System	18 Oct 2020 04:06:00

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:49', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '72ffbb6a-0cb7-4981-8ad2-b942370555bc'	System	18 Oct 2020 04:06:00
User entered 'None (0)'	System	18 Oct 2020 04:06:00

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:51', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '72ffbb6a-0cb7-4981-8ad2-b942370555bc'	System	18 Oct 2020 04:06:00
User entered 'No (N)'	System	18 Oct 2020 04:06:00

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-18T00:05:56', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '72ffbb6a-0cb7-4981-8ad2-b942370555bc'	System	18 Oct 2020 04:06:00
User entered '18 Oct 2020 00:05'	System	18 Oct 2020 04:06:00

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 4'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 5'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:26', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3e6d6d15-9909-4ac7-8a28-74e03dd1815d'	System	20 Oct 2020 00:29:45
User entered 'None (0)'	System	20 Oct 2020 00:29:45

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:28', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3e6d6d15-9909-4ac7-8a28-74e03dd1815d' User entered 'None (0)'	System	20 Oct 2020 00:29:45
	System	20 Oct 2020 00:29:45

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:30', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3e6d6d15-9909-4ac7-8a28-74e03dd1815d' User entered 'None (0)'	System	20 Oct 2020 00:29:45
	System	20 Oct 2020 00:29:45

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:32', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3e6d6d15-9909-4ac7-8a28-74e03dd1815d' User entered 'None (0)'	System	20 Oct 2020 00:29:45
	System	20 Oct 2020 00:29:45

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:34', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3e6d6d15-9909-4ac7-8a28-74e03dd1815d' User entered 'None (0)'	System	20 Oct 2020 00:29:45
	System	20 Oct 2020 00:29:45

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:36', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3e6d6d15-9909-4ac7-8a28-74e03dd1815d' User entered 'None (0)'	System	20 Oct 2020 00:29:45
	System	20 Oct 2020 00:29:45

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:39', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3e6d6d15-9909-4ac7-8a28-74e03dd1815d'	System	20 Oct 2020 00:29:45
User entered 'No (N)'	System	20 Oct 2020 00:29:45

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-19T20:29:41', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '3e6d6d15-9909-4ac7-8a28-74e03dd1815d' User entered '19 Oct 2020 20:29'	System	20 Oct 2020 00:29:45
	System	20 Oct 2020 00:29:45

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 6'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:07:21', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e30d9c3d-f815-4c09-80d7-41ee3b6f8a6d'	System	20 Oct 2020 22:07:50
User entered 'None (0)'	System	20 Oct 2020 22:07:50

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:07:23', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e30d9c3d-f815-4c09-80d7-41ee3b6f8a6d'	System	20 Oct 2020 22:07:50
User entered 'None (0)'	System	20 Oct 2020 22:07:50

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:07:25', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e30d9c3d-f815-4c09-80d7-41ee3b6f8a6d'	System	20 Oct 2020 22:07:50
User entered 'None (0)'	System	20 Oct 2020 22:07:50

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:07:27', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e30d9c3d-f815-4c09-80d7-41ee3b6f8a6d'	System	20 Oct 2020 22:07:50
User entered 'None (0)'	System	20 Oct 2020 22:07:50

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:07:29', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e30d9c3d-f815-4c09-80d7-41ee3b6f8a6d'	System	20 Oct 2020 22:07:50
User entered 'None (0)'	System	20 Oct 2020 22:07:50

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:07:31', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e30d9c3d-f815-4c09-80d7-41ee3b6f8a6d'	System	20 Oct 2020 22:07:50
User entered 'None (0)'	System	20 Oct 2020 22:07:50

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:07:43', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e30d9c3d-f815-4c09-80d7-41ee3b6f8a6d'	System	20 Oct 2020 22:07:50
User entered 'No (N)'	System	20 Oct 2020 22:07:50

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-20T18:07:46', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e30d9c3d-f815-4c09-80d7-41ee3b6f8a6d'	System	20 Oct 2020 22:07:50
User entered '20 Oct 2020 18:07'	System	20 Oct 2020 22:07:50

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	15 Oct 2020 17:26:34
User entered 'Day 7'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:40:30', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '98232587-c74d-496a-bfbc-a3995be71e7e'	System	21 Oct 2020 21:42:10
User entered 'None (0)'	System	21 Oct 2020 21:42:10

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:40:32', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '98232587-c74d-496a-bfbc-a3995be71e7e'	System	21 Oct 2020 21:42:10
User entered 'None (0)'	System	21 Oct 2020 21:42:10

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:40:34', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '98232587-c74d-496a-bfbc-a3995be71e7e'	System	21 Oct 2020 21:42:10
User entered 'None (0)'	System	21 Oct 2020 21:42:10

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:40:37', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '98232587-c74d-496a-bfbc-a3995be71e7e'	System	21 Oct 2020 21:42:10
User entered 'None (0)'	System	21 Oct 2020 21:42:10

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:40:39', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '98232587-c74d-496a-bfbc-a3995be71e7e'	System	21 Oct 2020 21:42:10
User entered 'None (0)'	System	21 Oct 2020 21:42:10

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:40:41', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '98232587-c74d-496a-bfbc-a3995be71e7e'	System	21 Oct 2020 21:42:10
User entered 'None (0)'	System	21 Oct 2020 21:42:10

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:40:46', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '98232587-c74d-496a-bfbc-a3995be71e7e'	System	21 Oct 2020 21:42:10
User entered 'No (N)'	System	21 Oct 2020 21:42:10

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-10-21T17:40:50', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '98232587-c74d-496a-bfbc-a3995be71e7e'	System	21 Oct 2020 21:42:10
User entered '21 Oct 2020 17:40'	System	21 Oct 2020 21:42:10

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 17:26:34

US3742357

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 17:26:34

US3742357

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:28:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Oct 2020 19:05:07

US3742357

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:28:27
User entered '23 Oct 2020'	(b) (4), (b) (6)	24 Oct 2020 19:05:07

US3742357

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:28:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Oct 2020 19:05:07

US3742357

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:28:27
User entered empty.	(b) (4), (b) (6)	24 Oct 2020 19:05:07

US3742357

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:28:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Oct 2020 19:05:14

US3742357

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'I'	System	24 Oct 2020 19:05:14

US3742357

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:29:12
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 18:10:15

US3742357

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:29:12
User entered '30 Oct 2020'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 18:10:15

US3742357

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:29:12
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 18:10:15

US3742357

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:29:12
User entered empty.	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 18:10:15

US3742357

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:29:18
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 18:10:20

US3742357

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'I'	System	30 Oct 2020 18:10:20

US3742357

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:29:51
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	06 Nov 2020 18:48:49

US3742357

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:29:51
User entered '6 Nov 2020'	Hassan Haji (b) (4) (b) (4)	06 Nov 2020 18:48:49

US3742357

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:29:51
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4) (b) (4)	06 Nov 2020 18:48:49

US3742357

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:29:51
User entered empty.	Hassan Haji (b) (4) (b) (4)	06 Nov 2020 18:48:49

US3742357

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:29:57
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	06 Nov 2020 18:48:54

US3742357

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'I'	System	06 Nov 2020 18:48:54

US3742357

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 19:45:14

US3742357

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:29
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 19:45:14

US3742357

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:29
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Nov 2020 19:45:14

US3742357

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'VISIT3'	System	17 Nov 2020 19:45:14

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:35
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:35
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:35
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered empty.	System	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:35
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:35
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:35
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:35
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered empty.	System	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:35
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered empty.	System	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:35
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered empty.	System	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:35
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered empty.	System	17 Nov 2020 19:45:18

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55

US3742357

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55

US3742357

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:56
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	17 Nov 2020 19:46:08
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	17 Nov 2020 19:45:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:45:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 19:45:29

US3742357

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:31:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:46:08
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 19:45:29

US3742357

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:32:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 19:46:20

US3742357

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:32:04
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 19:46:20

US3742357

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:32:04
User entered '13:25'	(b) (4), (b) (6)	17 Nov 2020 19:46:20

US3742357

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered '16 Nov 2020 13:25'	System	17 Nov 2020 19:46:20

US3742357

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:32:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 19:46:24

US3742357

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered '1'	System	17 Nov 2020 19:46:24

US3742357

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered 'Day 64'	System	17 Sep 2020 18:17:38

US3742357

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-11-17T17:12:48', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'dfbeddce-b376-4f78-9792-73eccc8ffad4'	System	17 Nov 2020 22:15:48
User entered 'Yes (Y)'	System	17 Nov 2020 22:15:48

US3742357

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-11-17T17:14:42', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'dfbeddce-b376-4f78-9792-73eccc8ffad4'	System	17 Nov 2020 22:15:48
User entered 'No (N)'	System	17 Nov 2020 22:15:48

US3742357

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-11-17T17:14:32', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'dfbeddce-b376-4f78-9792-73eccc8ffad4'	System	17 Nov 2020 22:15:48
User entered 'No (N)'	System	17 Nov 2020 22:15:48

US3742357

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-11-17T17:15:20', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'dfbeddce-b376-4f78-9792-73eccc8ffad4'	System	17 Nov 2020 22:15:48
User entered 'No (N)'	System	17 Nov 2020 22:15:48

US3742357

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-11-17T17:15:45', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'dfbeddce-b376-4f78-9792-73eccc8ffad4'	System	17 Nov 2020 22:15:48
User entered '17 Nov 2020 17:15:45'	System	17 Nov 2020 22:15:48

US3742357

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered '17 Nov 2020 00:01'	System	17 Sep 2020 18:17:38

US3742357

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:45:33
Data entry locked.	System	17 Sep 2020 18:17:38
User entered '21 Nov 2020 23:59'	System	17 Sep 2020 18:17:38

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2020-11-21T10:18:31', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '73dc998a-f445-4d66-9575-f5361fdd7036'	System	21 Nov 2020 15:19:09
User entered 'No (N)'	System	21 Nov 2020 15:19:09

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2020-11-21T10:18:37', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '73dc998a-f445-4d66-9575-f5361fdd7036'	System	21 Nov 2020 15:19:09
User entered 'No (N)'	System	21 Nov 2020 15:19:09

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-11-21T10:19:06', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '73dc998a-f445-4d66-9575-f5361fdd7036'	System	21 Nov 2020 15:19:09
User entered '21 Nov 2020 10:19:06'	System	21 Nov 2020 15:19:09

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 (4d5ba0718386530c)', Time: '2020-11-29T06:50:05', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '88aa305f-6804-4093-8b34-8bfd3abd8223'	System	29 Nov 2020 11:50:26
User entered 'No (N)'	System	29 Nov 2020 11:50:26

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2020-11-29T06:50:13', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '88aa305f-6804-4093-8b34-8bfd3abd8223'	System	29 Nov 2020 11:50:26
User entered 'No (N)'	System	29 Nov 2020 11:50:26

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-11-29T06:50:20', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '88aa305f-6804-4093-8b34-8bfd3abd8223'	System	29 Nov 2020 11:50:26
User entered '29 Nov 2020 06:50:20'	System	29 Nov 2020 11:50:26

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2020-12-07T10:19:24', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'd29a79f8-0683-42b8-baa9-1af479682b7e'	System	07 Dec 2020 15:20:01
User entered 'No (N)'	System	07 Dec 2020 15:20:01

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2020-12-07T10:19:33', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'd29a79f8-0683-42b8-baa9-1af479682b7e'	System	07 Dec 2020 15:20:01
User entered 'Yes (Y)'	System	07 Dec 2020 15:20:01

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Please 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 (4d5ba0718386530c)', Time: '2020-12-07T10:19:43', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'd29a79f8-0683-42b8-baa9-1af479682b7e'	System	07 Dec 2020 15:20:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Dec 2020 15:20:01

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-12-07T10:19:51', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'd29a79f8-0683-42b8-baa9-1af479682b7e'	System	07 Dec 2020 15:20:01
User entered '07 Dec 2020 10:19:51'	System	07 Dec 2020 15:20:01

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2020-12-16T08:40:25', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '4a4f7922-606b-40ec-85ee-8519b66c7b80'	System	16 Dec 2020 13:41:32
User entered 'Yes (Y)'	System	16 Dec 2020 13:41:32

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2020-12-16T08:40:54', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '4a4f7922-606b-40ec-85ee-8519b66c7b80'	System	16 Dec 2020 13:41:32
User entered 'No (N)'	System	16 Dec 2020 13:41:32

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2020-12-16T08:41:01', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '4a4f7922-606b-40ec-85ee-8519b66c7b80'	System	16 Dec 2020 13:41:32
User entered 'No (N)'	System	16 Dec 2020 13:41:32

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2020-12-16T08:41:23', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '4a4f7922-606b-40ec-85ee-8519b66c7b80'	System	16 Dec 2020 13:41:32
User entered 'No (N)'	System	16 Dec 2020 13:41:32

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-12-16T08:41:27', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '4a4f7922-606b-40ec-85ee-8519b66c7b80'	System	16 Dec 2020 13:41:32
User entered '16 Dec 2020 08:41:27'	System	16 Dec 2020 13:41:32

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2020-12-19T10:52:57', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'a4502958-762a-4902-ac03-885dc0da2c93'	System	19 Dec 2020 15:53:12
User entered 'No (N)'	System	19 Dec 2020 15:53:12

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2020-12-19T10:53:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'a4502958-762a-4902-ac03-885dc0da2c93'	System	19 Dec 2020 15:53:12
User entered 'No (N)'	System	19 Dec 2020 15:53:12

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-12-19T10:53:07', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'a4502958-762a-4902-ac03-885dc0da2c93'	System	19 Dec 2020 15:53:12
User entered '19 Dec 2020 10:53:07'	System	19 Dec 2020 15:53:12

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2020-12-30T09:35:52', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '41d6503d-bafe-4bb6-a241-8e0d4ced75c7'	System	30 Dec 2020 14:36:22
User entered 'Yes (Y)'	System	30 Dec 2020 14:36:22

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2020-12-30T09:36:01', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '41d6503d-bafe-4bb6-a241-8e0d4ced75c7'	System	30 Dec 2020 14:36:22
User entered 'No (N)'	System	30 Dec 2020 14:36:22

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2020-12-30T09:36:07', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '41d6503d-bafe-4bb6-a241-8e0d4ced75c7'	System	30 Dec 2020 14:36:22
User entered 'No (N)'	System	30 Dec 2020 14:36:22

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2020-12-30T09:36:15', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '41d6503d-bafe-4bb6-a241-8e0d4ced75c7'	System	30 Dec 2020 14:36:22
User entered 'No (N)'	System	30 Dec 2020 14:36:22

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2020-12-30T09:36:18', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '41d6503d-bafe-4bb6-a241-8e0d4ced75c7'	System	30 Dec 2020 14:36:22
User entered '30 Dec 2020 09:36:18'	System	30 Dec 2020 14:36:22

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-01-02T19:05:06', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f6929eec-9c3c-4f37-a996-578f15dbf4a7'	System	03 Jan 2021 00:05:16
User entered 'No (N)'	System	03 Jan 2021 00:05:16

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-01-02T19:05:10', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f6929eec-9c3c-4f37-a996-578f15dbf4a7'	System	03 Jan 2021 00:05:16
User entered 'No (N)'	System	03 Jan 2021 00:05:16

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-01-02T19:05:14', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f6929eec-9c3c-4f37-a996-578f15dbf4a7'	System	03 Jan 2021 00:05:16
User entered '02 Jan 2021 19:05:14'	System	03 Jan 2021 00:05:16

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-01-11T22:11:46', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '921d97fc-27e7-4a7a-ae25-2797b1f1f99f'	System	12 Jan 2021 03:11:59
User entered 'No (N)'	System	12 Jan 2021 03:11:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-01-11T22:11:50', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '921d97fc-27e7-4a7a-ae25-2797b1f1f99f'	System	12 Jan 2021 03:11:59
User entered 'No (N)'	System	12 Jan 2021 03:11:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-01-11T22:11:53', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '921d97fc-27e7-4a7a-ae25-2797b1f1f99f' User entered '11 Jan 2021 22:11:53'	System	12 Jan 2021 03:11:59

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 (4d5ba0718386530c)', Time: '2021-01-27T12:06:32', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '1f9909c1-85d5-4747-9161-51266a1e2727'	System	27 Jan 2021 15:07:04
User entered 'No (N)'	System	27 Jan 2021 15:07:04

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-01-27T12:06:55', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '1f9909c1-85d5-4747-9161-51266a1e2727'	System	27 Jan 2021 15:07:04
User entered 'No (N)'	System	27 Jan 2021 15:07:04

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-01-27T12:06:59', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '1f9909c1-85d5-4747-9161-51266a1e2727'	System	27 Jan 2021 15:07:04
User entered '27 Jan 2021 12:06:59'	System	27 Jan 2021 15:07:04

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-01-31T18:43:26', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '32d2373f-6f96-43b7-a21b-3c76c748279b'	System	31 Jan 2021 21:43:12
User entered 'No (N)'	System	31 Jan 2021 21:43:12

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-01-31T18:43:30', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '32d2373f-6f96-43b7-a21b-3c76c748279b'	System	31 Jan 2021 21:43:12
User entered 'No (N)'	System	31 Jan 2021 21:43:12

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-01-31T18:43:33', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '32d2373f-6f96-43b7-a21b-3c76c748279b' User entered '31 Jan 2021 18:43:33'	System	31 Jan 2021 21:43:12
	System	31 Jan 2021 21:43:12

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-02-07T12:20:25', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e8ca4886-aad8-4041-921d-967b588d46fe'	System	07 Feb 2021 17:20:37
User entered 'No (N)'	System	07 Feb 2021 17:20:37

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-02-07T12:20:29', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e8ca4886-aad8-4041-921d-967b588d46fe'	System	07 Feb 2021 17:20:37
User entered 'No (N)'	System	07 Feb 2021 17:20:37

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-02-07T12:20:32', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'e8ca4886-aad8-4041-921d-967b588d46fe'	System	07 Feb 2021 17:20:37
User entered '07 Feb 2021 12:20:32'	System	07 Feb 2021 17:20:37

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 (4d5ba0718386530c)', Time: '2021-02-14T12:40:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '0f3d8ad6-067a-4b01-9309-d016480e461a'	System	14 Feb 2021 17:40:39
User entered 'Yes (Y)'	System	14 Feb 2021 17:40:39

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-02-14T12:40:05', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '0f3d8ad6-067a-4b01-9309-d016480e461a'	System	14 Feb 2021 17:40:39
User entered 'No (N)'	System	14 Feb 2021 17:40:39

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-02-14T12:40:09', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '0f3d8ad6-067a-4b01-9309-d016480e461a'	System	14 Feb 2021 17:40:39
User entered 'No (N)'	System	14 Feb 2021 17:40:39

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-02-14T12:40:32', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '0f3d8ad6-067a-4b01-9309-d016480e461a'	System	14 Feb 2021 17:40:39
User entered 'No (N)'	System	14 Feb 2021 17:40:39

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-02-14T12:40:35', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '0f3d8ad6-067a-4b01-9309-d016480e461a'	System	14 Feb 2021 17:40:39
User entered '14 Feb 2021 12:40:35'	System	14 Feb 2021 17:40:39

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-02-24T07:56:17-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f43f0185-40b0-41b8-b732-f7940ee7379c'	System	24 Feb 2021 12:56:40
User entered 'Yes (Y)'	System	24 Feb 2021 12:56:40

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-02-24T07:56:21-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f43f0185-40b0-41b8-b732-f7940ee7379c'	System	24 Feb 2021 12:56:40
User entered 'No (N)'	System	24 Feb 2021 12:56:40

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

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 (4d5ba0718386530c)', Time: '2021-02-24T07:56:26-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f43f0185-40b0-41b8-b732-f7940ee7379c'	System	24 Feb 2021 12:56:40
User entered 'No (N)'	System	24 Feb 2021 12:56:40

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-02-24T07:56:32-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f43f0185-40b0-41b8-b732-f7940ee7379c' User entered 'No (N)'	System	24 Feb 2021 12:56:40
	System	24 Feb 2021 12:56:40

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-02-24T07:56:35-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'f43f0185-40b0-41b8-b732-f7940ee7379c'	System	24 Feb 2021 12:56:40
User entered '24 Feb 2021 07:56:35'	System	24 Feb 2021 12:56:40

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-02-27T10:11:18-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '2fb800c8-6fbe-46d4-82a7-2b4a1b8a5bc9' User entered 'No (N)'	System	27 Feb 2021 15:11:30
	System	27 Feb 2021 15:11:30

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-02-27T10:11:24-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '2fb800c8-6fbe-46d4-82a7-2b4a1b8a5bc9'	System	27 Feb 2021 15:11:30
User entered 'No (N)'	System	27 Feb 2021 15:11:30

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-02-27T10:11:27-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '2fb800c8-6fbe-46d4-82a7-2b4a1b8a5bc9' User entered '27 Feb 2021 10:11:27'	System	27 Feb 2021 15:11:30
	System	27 Feb 2021 15:11:30

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-03-09T12:04:57-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '20f32c89-8565-48eb-9a81-b1b04e7fa3f7'	System	09 Mar 2021 17:16:52
User entered 'No (N)'	System	09 Mar 2021 17:16:52

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-03-09T12:05:01-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '20f32c89-8565-48eb-9a81-b1b04e7fa3f7'	System	09 Mar 2021 17:16:52
User entered 'No (N)'	System	09 Mar 2021 17:16:52

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-03-09T12:05:04-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '20f32c89-8565-48eb-9a81-b1b04e7fa3f7'	System	09 Mar 2021 17:16:52
User entered '09 Mar 2021 12:05:04'	System	09 Mar 2021 17:16:52

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-03-15T18:15:46-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '113d45c4-024a-4903-a66c-dede63098424'	System	15 Mar 2021 22:15:57
User entered 'No (N)'	System	15 Mar 2021 22:15:57

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-03-15T18:15:50-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '113d45c4-024a-4903-a66c-dede63098424'	System	15 Mar 2021 22:15:57
User entered 'No (N)'	System	15 Mar 2021 22:15:57

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-03-15T18:15:53-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '113d45c4-024a-4903-a66c-dede63098424'	System	15 Mar 2021 22:15:57
User entered '15 Mar 2021 18:15:53'	System	15 Mar 2021 22:15:57

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-03-24T08:37:26-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ea0f23a0-62af-4826-a55b-4fa678dd007c'	System	24 Mar 2021 12:37:39
User entered 'No (N)'	System	24 Mar 2021 12:37:39

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-03-24T08:37:30-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ea0f23a0-62af-4826-a55b-4fa678dd007c'	System	24 Mar 2021 12:37:39
User entered 'No (N)'	System	24 Mar 2021 12:37:39

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-03-24T08:37:32-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ea0f23a0-62af-4826-a55b-4fa678dd007c' User entered '24 Mar 2021 08:37:32'	System	24 Mar 2021 12:37:39
	System	24 Mar 2021 12:37:39

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-03-31T13:37:41-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '01ab2336-f837-4790-b762-ead6bc530cac'	System	31 Mar 2021 17:38:01
User entered 'No (N)'	System	31 Mar 2021 17:38:01

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-03-31T13:37:45-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '01ab2336-f837-4790-b762-ead6bc530cac'	System	31 Mar 2021 17:38:01
User entered 'No (N)'	System	31 Mar 2021 17:38:01

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-03-31T13:37:53-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '01ab2336-f837-4790-b762-ead6bc530cac' User entered '31 Mar 2021 13:37:53'	System	31 Mar 2021 17:38:01
	System	31 Mar 2021 17:38:01

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-04-05T08:25:28-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'd6e14599-78c3-42f6-b025-45c36c4e8edd' User entered 'No (N)'	System	05 Apr 2021 12:25:36
	System	05 Apr 2021 12:25:36

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-04-05T08:25:30-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'd6e14599-78c3-42f6-b025-45c36c4e8edd'	System	05 Apr 2021 12:25:36
User entered 'No (N)'	System	05 Apr 2021 12:25:36

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-04-05T08:25:33-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'd6e14599-78c3-42f6-b025-45c36c4e8edd' User entered '05 Apr 2021 08:25:33'	System	05 Apr 2021 12:25:36
	System	05 Apr 2021 12:25:36

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-04-10T09:25:10-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ebfad3b6-dd91-4a19-a3a0-34a7b2ae2435'	System	10 Apr 2021 13:25:19
User entered 'No (N)'	System	10 Apr 2021 13:25:19

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-04-10T09:25:14-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ebfad3b6-dd91-4a19-a3a0-34a7b2ae2435'	System	10 Apr 2021 13:25:19
User entered 'No (N)'	System	10 Apr 2021 13:25:19

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-04-10T09:25:16-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: 'ebfad3b6-dd91-4a19-a3a0-34a7b2ae2435'	System	10 Apr 2021 13:25:19
User entered '10 Apr 2021 09:25:16'	System	10 Apr 2021 13:25:19

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-04-17T09:40:24-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '592df99e-dd8a-41e7-87c1-54f99e529353'	System	17 Apr 2021 13:40:32
User entered 'No (N)'	System	17 Apr 2021 13:40:32

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-04-17T09:40:26-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '592df99e-dd8a-41e7-87c1-54f99e529353'	System	17 Apr 2021 13:40:32
User entered 'No (N)'	System	17 Apr 2021 13:40:32

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-04-17T09:40:29-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '592df99e-dd8a-41e7-87c1-54f99e529353'	System	17 Apr 2021 13:40:32
User entered '17 Apr 2021 09:40:29'	System	17 Apr 2021 13:40:32

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[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 (4d5ba0718386530c)', Time: '2021-05-01T09:29:33-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '272cfb6e-668a-4d20-85c9-d6337ac0ec85'	System	01 May 2021 13:29:43
User entered 'No (N)'	System	01 May 2021 13:29:43

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

Have you been exposed to someone with 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 (4d5ba0718386530c)', Time: '2021-05-01T09:29:37-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '272cfb6e-668a-4d20-85c9-d6337ac0ec85'	System	01 May 2021 13:29:43
User entered 'No (N)'	System	01 May 2021 13:29:43

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-05-01T09:29:40-04:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '272cfb6e-668a-4d20-85c9-d6337ac0ec85'	System	01 May 2021 13:29:43
User entered '01 May 2021 09:29:40'	System	01 May 2021 13:29:43

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 08:22:06

US3742357

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:22:06
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 08:22:06

US3742357

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:27:48

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:14:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-03-09T12:04:32-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '59e0f8c1-63c4-499a-a6f1-87aa6fc13c51'	System	09 Mar 2021 17:16:32
User entered 'Yes (Y)'	System	09 Mar 2021 17:16:32

US3742357

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:27:48

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:14:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-03-09T12:04:43-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '59e0f8c1-63c4-499a-a6f1-87aa6fc13c51'	System	09 Mar 2021 17:16:32
User entered 'Yes (Y)'	System	09 Mar 2021 17:16:32

US3742357

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:27:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:14:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4d5ba0718386530c)', Time: '2021-03-09T12:04:47-05:00', User OID: 'PatientReportedOutcome (US3742357)', ODM File OID: '59e0f8c1-63c4-499a-a6f1-87aa6fc13c51' User entered '09 Mar 2021 12:04:47'	System	09 Mar 2021 17:16:32
	System	09 Mar 2021 17:16:32

US3742357

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:00:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Feb 2021 15:49:18

US3742357

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:00:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Feb 2021 15:49:18

US3742357

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:00:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Feb 2021 15:49:18

US3742357

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:00:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Feb 2021 15:49:18

US3742357

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:00:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Feb 2021 15:49:24

US3742357

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:45:55
User entered 'I'	System	11 Feb 2021 15:49:24

US3742357

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:59:45
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:59:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Feb 2021 15:50:02

US3742357

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:59:45
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:59:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Feb 2021 15:50:02

US3742357

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:59:45
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:59:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Feb 2021 15:50:02

US3742357

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:59:45
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:59:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Feb 2021 15:50:02

US3742357

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:59:45
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:59:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Feb 2021 15:50:08

US3742357

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:59:45
User entered 'I'	System	11 Feb 2021 15:50:08

US3742357

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:59:45
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:58:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Feb 2021 15:50:26

US3742357

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:59:45
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:58:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
User entered '9 Feb 2021'	Sherry McCammon (b) (4)	11 Feb 2021 15:50:26

US3742357

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:59:45
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:58:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Feb 2021 15:50:26

US3742357

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:59:45
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:58:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:08:00
User entered empty.	(b) (4) Sherry McCammon (b) (4)	11 Feb 2021 15:50:26

US3742357

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:59:45
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:58:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Feb 2021 15:50:33

US3742357

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:59:45
User entered '1'	System	11 Feb 2021 15:50:33

US3742357

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:58:59
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:41:06
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	16 Mar 2021 16:57:40
	(b) (4)	

US3742357

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:58:59
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:41:06
	(b) (4)	
User entered '12 Mar 2021'	Sherry McCammon (b) (4)	16 Mar 2021 16:57:40
	(b) (4)	

US3742357

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:58:59
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:41:06
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	16 Mar 2021 16:57:40
	(b) (4)	

US3742357

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:58:59
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:41:06
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	16 Mar 2021 16:57:40
	(b) (4)	

US3742357

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:59:15
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:41:06
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	16 Mar 2021 16:57:54
	(b) (4)	

US3742357

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:47
User entered 'I'	System	16 Mar 2021 16:57:54

US3742357

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:19

US3742357

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:19

US3742357

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:19

US3742357

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	23 Apr 2021 13:17:19

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 13:17:24

US3742357

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:29

US3742357

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:29

US3742357

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:18:17

US3742357

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:18:17

US3742357

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '12:54'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:18:17

US3742357

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Apr 2021 12:54'	System	23 Apr 2021 13:18:17

US3742357

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:18:21

US3742357

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 13:18:21

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:27:48

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:28
User entered '08 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:50:30

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:27:48

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:28
User entered '10:10'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:50:30

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:27:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:14
User entered '08 Dec 2020 10:10'	System	08 Dec 2020 20:50:30

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:27:48

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:28
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:50:30

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:27:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:28
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:50:30

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 1 (Day 1)'	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered '05 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:27

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Per CDM: Assessment Not Done is checked yet data present for Day 1. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:18:41
Query 'Per CDM: Assessment Not Done is checked yet data present for Day 1. Please review and reconcile.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 17:48:24
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:48:02
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:48:02
User opened query 'Per CDM: Assessment Not Done is checked yet data present for Day 1. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 13:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered '1' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:53:02
User entered '0'	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Per CDM: It appears that O2 were not collected for Days 1-3 and Temperature Day 1' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 14:18:53
Query 'Per CDM: It appears that O2 were not collected for Days 1-3 and Temperature Day 1' answered with 'ND- NOT DONE ENTERED' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 17:48:40
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:48:02
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:48:02
User opened query 'Per CDM: It appears that O2 were not collected for Days 1-3 and Temperature Day 1' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 13:55:48
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered empty.	Sherry McCammon (b) (4)	08 Dec 2020 20:51:27

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User entered '%'	System	25 Jan 2021 17:48:02
User entered empty.	System	08 Dec 2020 20:51:27

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:48:02
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:48:02
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:27

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:55:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:55:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'Severe (Severe)' reason for change:	Sherry McCammon (b) (4)	08 Dec 2020 20:53:54
Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:24
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:24
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:24
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:53:54
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:53:54
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:57
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:57
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:59:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:59:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 2 (Day 2)' reason for change:	(b) (4)	
Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:52:04
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered '06 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:35

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered '0'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:35

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:48:02
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:48:02
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:35

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User entered '%'	System	25 Jan 2021 17:48:02
User entered empty.	System	08 Dec 2020 20:51:35

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered '99.7' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:53:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:55:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:55:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:55:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:24
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:24
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:24
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:53:54
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:53:54
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:57
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:57
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:59:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:59:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:35
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 3 (Day 3)' reason for change:	(b) (4)	
Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:52:04
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered '07 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:44

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered '0'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:44

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:48:02
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:48:02
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered empty.	Sherry McCammon (b) (4)	08 Dec 2020 20:51:44

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User entered '%'	System	25 Jan 2021 17:48:02
User entered empty.	System	08 Dec 2020 20:51:44

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered '97.4' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:53:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Form: Symptom Log (3)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Form: Symptom Log (3)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Form: Symptom Log (3)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:55:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:55:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Form: Symptom Log (3)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:55:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Form: Symptom Log (3)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:24
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Form: Symptom Log (3)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:24
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:24
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:53:54
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:53:54
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:57
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:57
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:59:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:59:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:44
	(b) (4)	

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Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 4 (Day 4)'	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55

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Form: Symptom Log (4)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered '08 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:55

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered '0'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:55

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered '96' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:53:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User entered '%'	System	08 Dec 2020 20:53:02
User entered empty.	System	08 Dec 2020 20:51:55

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered '98.5' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:53:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:54:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:55:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:55:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:55:36
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:24
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Form: Symptom Log (4)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:24
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:24
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Form: Symptom Log (4)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:53:54
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:53:54
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Form: Symptom Log (4)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:57
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:56:57
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:59:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:53
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:59:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:51:55
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 5 (Day 5)'	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 13:05:52

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '09 Dec 2020'	(b) (4) Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 13:05:52

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '0'	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '96' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:26
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User entered '%'	System	15 Dec 2020 13:07:26
User entered empty.	System	15 Dec 2020 13:05:52

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '97.9' F reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:08:04
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:08:47
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:08:47
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:08:47
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:35:22
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:09:41
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:09:41
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:36:15
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:36:15
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:36:15
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:37:09
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:37:09
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:37:09
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:38:01
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:38:01
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:38:01
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:38:01
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:05:52
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 6 (Day 6)'	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 13:06:10

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '10 Dec 2020'	(b) (4) Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 13:06:10

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Form: Symptom Log (6)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '0'	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:26
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User entered '%'	System	15 Dec 2020 13:07:26
User entered empty.	System	15 Dec 2020 13:06:10

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '92.6' F reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:08:04
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:08:47
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:08:47
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:08:47
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:35:22
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:09:41
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:09:41
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:36:15
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:36:15
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:36:15
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:37:09
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:37:09
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:37:09
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:38:01
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:38:01
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:38:01
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:38:01
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:06:10
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 7 (Day 7)'	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 13:07:06

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '11 Dec 2020'	(b) (4) Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 13:07:06

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '0'	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:26
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
User entered '%'	System	15 Dec 2020 13:07:26
User entered empty.	System	15 Dec 2020 13:07:06

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '97.5' F reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:08:04
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:08:47
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:08:47
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:08:47
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:35:22
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:35:22
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:09:41
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:36:15
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:36:15
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:36:15
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:37:09
	(b) (4)	15 Dec 2020 13:07:06

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:37:09
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:37:09
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:38:01
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	(b) (4)
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:38:01
	(b) (4)	15 Dec 2020 13:07:06

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:38:01
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:29:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:38:01
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 13:07:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:27:36
User entered '08 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:01

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:27:40
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:01

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:21:11
User closed query 'Per CDM RQ: Please update when data is available. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 18:36:37
Query 'Per CDM RQ: Please update when data is available. Thank you.' answered with 'updated' (Site from DM).	Sherry McCammon (b) (4)	15 Dec 2020 13:38:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	15 Dec 2020 13:38:40
User opened query 'Per CDM RQ: Please update when data is available. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 11:49:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 11:48:50
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	Kaitlin Mason (b) (4)	09 Dec 2020 18:58:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	08 Dec 2020 20:51:01
	Sherry McCammon (b) (4)	08 Dec 2020 20:51:01
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:27:44
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Dec 2020 18:58:51
User entered '08 Dec 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	09 Dec 2020 18:58:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Dec 2020 20:51:01
User entered '88 Dec 2020' (non-conformant).	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:01

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Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:21:11
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:01

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Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:21:11
User entered empty.	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:01

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:27:48
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	09 Dec 2020 18:58:51
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:01

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:27:53
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Dec 2020 18:58:51
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Dec 2020 20:51:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:01

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:27:56
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Dec 2020 18:58:51
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Dec 2020 20:51:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:51:01

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:28
User entered '0'	System	15 Dec 2020 13:38:40

US3742357

Folder: Covid-19 Assessment 08 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:27:48

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:21:21
DataPoint Un-verified.	Sherry McCammon (b) (4)	07 Jan 2021 18:06:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 17:29:46
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Dec 2020 20:51:12

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:27:48

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:21:29
User entered '28 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:11:20

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:27:48

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:21:29
User entered '14:15'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:11:20

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:27:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:48
User entered '28 Dec 2020 14:15'	System	07 Jan 2021 18:11:20

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:27:48

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:21:29
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:11:20

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:27:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:21:29
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:11:20

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 28 Dec 2020 symptom log on log line 1. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 11:58:39
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 28 Dec 2020 symptom log on log line 1. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 20:46:16
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 28 Dec 2020 symptom log on log line 1. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 06:58:32
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 1 (Day 1)'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:11:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '24 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:11:47

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:11:47

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:57
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:34
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:46:01
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:46:01
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Kaitlin Mason (b) (4)	20 Apr 2021 20:46:01
User signature succeeded.	(b) (4)	
	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	20 Apr 2021 20:46:01
User entered empty.	System	07 Jan 2021 18:11:47

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:57
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:34
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:46:01
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:46:01
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Kaitlin Mason (b) (4)	20 Apr 2021 20:46:01
User signature succeeded.	(b) (4)	
	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:22:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:39
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:19:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:47
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 28 Dec 2020 symptom log on log line 2. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 11:58:47
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 28 Dec 2020 symptom log on log line 2. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 20:47:18
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 28 Dec 2020 symptom log on log line 2. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 07:01:24
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 2 (Day 2)'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:11:57

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '25 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:11:57

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:11:57

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:57
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:34
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:46:56
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:46:56
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered empty.	Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	20 Apr 2021 20:46:56
User entered empty.	System	07 Jan 2021 18:11:57

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:57
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:34
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:46:56
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:46:56
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered empty.	Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:22:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:39
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:19:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:11:57
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 28 Dec 2020 symptom log on log line 3. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 11:58:58
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 28 Dec 2020 symptom log on log line 3. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 20:48:30
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 28 Dec 2020 symptom log on log line 3. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 07:04:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 3 (Day 3)'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:12:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '26 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:12:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:12:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:57
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:34
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:47:53
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:47:53
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Kaitlin Mason (b) (4)	20 Apr 2021 20:47:53
User signature succeeded.	(b) (4)	
	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	20 Apr 2021 20:47:53
User entered empty.	System	07 Jan 2021 18:12:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:57
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:34
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:47:53
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:47:53
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered empty.	Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:22:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:39
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Form: Symptom Log (3)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Form: Symptom Log (3)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:19:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Form: Symptom Log (3)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Form: Symptom Log (3)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:09
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 28 Dec 2020 symptom log on log line 4. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 11:59:06
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 28 Dec 2020 symptom log on log line 4. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 20:49:22
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 28 Dec 2020 symptom log on log line 4. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 07:04:23
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 4 (Day 4)'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:12:28

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '27 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:12:28

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:12:28

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:57
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:34
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:49:44
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:49:44
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Kaitlin Mason (b) (4)	20 Apr 2021 20:49:44
User signature succeeded.	(b) (4)	
	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Form: Symptom Log (4)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	20 Apr 2021 20:49:44
User entered empty.	System	07 Jan 2021 18:12:28

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:10:57
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:34
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:49:44
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 20:49:44
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Kaitlin Mason (b) (4)	20 Apr 2021 20:49:44
User signature succeeded.	(b) (4)	
	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered empty.		
	Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:22:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:39
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Form: Symptom Log (4)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28

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Form: Symptom Log (4)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:19:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:28
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 5 (Day 5)'	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '28 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:12:44

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:12:44

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:15:47
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	07 Jan 2021 18:15:47
User entered empty.	System	07 Jan 2021 18:12:44

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '98.0' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:16:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:22:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:19:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:44
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 6 (Day 6)'	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58

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Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '29 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:12:58

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:12:58

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '95' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:15:47
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	07 Jan 2021 18:15:47
User entered empty.	System	07 Jan 2021 18:12:58

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '97.8' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:16:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:22:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:20
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:19:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:12:58
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 7 (Day 7)'	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '30 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:13:15

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Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	07 Jan 2021 18:13:15

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '95' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:15:47
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	07 Jan 2021 18:15:47
User entered empty.	System	07 Jan 2021 18:13:15

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '96.5' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:16:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:22:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:18:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:23:20
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:24:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:19:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

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Form: Symptom Log (7)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:25:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:20:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

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Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

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Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:27:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

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Form: Symptom Log (7)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Jan 2021 18:26:22
User entered empty.	(b) (4) Sherry McCammon (b) (4)	07 Jan 2021 18:13:15

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 8 (Day 8)'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '31 Dec 2020'	Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '95' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:53:52
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	13 Jan 2021 16:53:52
User entered empty.	System	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

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Form: Symptom Log (8)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '97.1' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:56:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

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Form: Symptom Log (8)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:02:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:00:11
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:48
DataPoint activated with code reason code Data required.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:45:22
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	07 Jan 2021 18:13:26

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 9 (Day 9)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '1 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:46:05

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:46:05

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '93' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:53:52
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	13 Jan 2021 16:53:52
User entered empty.	System	13 Jan 2021 16:46:05

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '98.1' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:56:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:02:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:00:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Form: Symptom Log (9)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:05
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 10 (Day 10)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '2 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:46:28

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:46:28

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '95' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:54:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	13 Jan 2021 16:54:56
User entered empty.	System	13 Jan 2021 16:46:28

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '97.1' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:56:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:02:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:00:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 11 (Day 11)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '3 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:46:49

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:46:49

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '97' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:54:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	13 Jan 2021 16:54:56
User entered empty.	System	13 Jan 2021 16:46:49

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '98.1' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:56:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:02:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(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)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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Form: Symptom Log (11)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(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)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:46:49
	(b) (4)	

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 12 (Day 12)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '4 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:47:05

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:47:05

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '96' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:54:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	13 Jan 2021 16:54:56
User entered empty.	System	13 Jan 2021 16:47:05

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Form: Symptom Log (12)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '97.3' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:56:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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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)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:02:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:16:59
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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Form: Symptom Log (12)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:05
	(b) (4)	

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 13 (Day 13)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '5 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:47:15

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:47:15

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '96' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:54:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Form: Symptom Log (13)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	13 Jan 2021 16:54:56
User entered empty.	System	13 Jan 2021 16:47:15

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Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '96.2' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:56:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:02:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:05:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Form: Symptom Log (13)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:00:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:15
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 14 (Day 14)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '6 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:47:28

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:47:28

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '95' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:54:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	13 Jan 2021 16:54:56
User entered empty.	System	13 Jan 2021 16:47:28

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '97.5' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:56:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:00:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:13:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:14:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:14:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Form: Symptom Log (14)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

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Form: Symptom Log (14)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:00:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:28
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 15 (Day 15)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '7 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:47:40

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:47:40

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '96' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:54:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	13 Jan 2021 16:54:56
User entered empty.	System	13 Jan 2021 16:47:40

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '97.9' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:58:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:02:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:13:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:14:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:14:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:47:40
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 16 (Day 16)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08

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Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '8 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:48:08

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:48:08

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '95' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:54:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	13 Jan 2021 16:54:56
User entered empty.	System	13 Jan 2021 16:48:08

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '96.9' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:58:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:00:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:13:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:14:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:14:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:21:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:08
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 17 (Day 17)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '9 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:48:18

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:48:18

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:54:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	13 Jan 2021 16:54:56
User entered empty.	System	13 Jan 2021 16:48:18

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '98.5' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:58:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:02:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:13:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:14:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:14:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Form: Symptom Log (17)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Form: Symptom Log (17)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 18 (Day 18)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27

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Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:27:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '10 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:48:27

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:48:27

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Form: Symptom Log (18)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '97' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:54:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	13 Jan 2021 16:54:56
User entered empty.	System	13 Jan 2021 16:48:27

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:27:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '97.6' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:58:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:02:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:13:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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Form: Symptom Log (18)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:14:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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Form: Symptom Log (18)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:14:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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Form: Symptom Log (18)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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Form: Symptom Log (18)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:27:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:27:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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Form: Symptom Log (18)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:27
	(b) (4)	

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Day 19 (Day 19)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '11 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:48:42

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Form: Symptom Log (19)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 16:48:42

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:27:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '97' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:54:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User entered '%'	System	13 Jan 2021 16:54:56
User entered empty.	System	13 Jan 2021 16:48:42

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Form: Symptom Log (19)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered '97.3' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 16:58:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:27:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:01:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:27:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:02:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:27:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:27:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:03:56
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:27:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:13:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:14:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:27:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:14:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Form: Symptom Log (19)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Form: Symptom Log (19)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:15:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Form: Symptom Log (19)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Form: Symptom Log (19)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Form: Symptom Log (19)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:19:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:27:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:27:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:20:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 16:48:42
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:25
User entered '28 Dec 2020'	(b) (4), (b) (6)	07 Jan 2021 21:34:49

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Jan 2021 21:34:49

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:25
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	29 Jan 2021 20:46:46
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Test result is positive.' (Site from System).	(b) (4), (b) (6)	07 Jan 2021 21:36:00
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	07 Jan 2021 21:34:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Jan 2021 21:34:49

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:25
User entered '28 Dec 2020'	(b) (4), (b) (6)	07 Jan 2021 21:34:49

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:25
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	07 Jan 2021 21:34:49

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:25
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 21:34:49

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Jan 2021 21:34:49

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:25
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 21:34:49

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:22:25
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 21:34:49

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:27:48

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:01
User entered 'I'	System	07 Jan 2021 21:34:49

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:03:36
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:41:06
User closed query 'Please verify as symptom log notes 93% on 01Jan2021. Update this field and the three following fields to reflect this.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:50:08
Query 'Please verify as symptom log notes 93% on 01Jan2021. Update this field and the three following fields to reflect this.' answered with 'updated' (Site from CRA).	Kaitlin Mason (b) (4) (b) (4)	30 Mar 2021 11:46:42
DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	30 Mar 2021 11:46:36
Signature has been broken.	Kaitlin Mason (b) (4) (b) (4)	30 Mar 2021 11:46:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	30 Mar 2021 11:46:36
User opened query 'Please verify as symptom log notes 93% on 01Jan2021. Update this field and the three following fields to reflect this.' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 15:55:15
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:04:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:41:06
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	30 Mar 2021 11:46:36
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	30 Mar 2021 11:46:36
User entered '01 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	30 Mar 2021 11:46:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:04:51
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:41:06
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	30 Mar 2021 11:46:36
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	30 Mar 2021 11:46:36
User entered '01 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	30 Mar 2021 11:46:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:04:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:41:06
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	30 Mar 2021 11:46:36
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	30 Mar 2021 11:46:36
User entered '93' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	30 Mar 2021 11:46:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04
	(b) (4)	

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)'	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Jan 2021 17:23:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 17:23:17
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:23:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Jan 2021 17:23:04
User entered empty.	System	13 Jan 2021 17:23:04
	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

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Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Generated On: 12 Aug 2021 13:27:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

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Generated On: 12 Aug 2021 13:27:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
User closed query 'Per CDM: Please review and provide responses for the questions relating to Evidence of Shock.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 10:42:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Query 'Per CDM: Please review and provide responses for the questions relating to Evidence of Shock.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	15 Feb 2021 16:40:18
User opened query 'Per CDM: Please review and provide responses for the questions relating to Evidence of Shock.' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 04:29:19
User entered 'No (N)'	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Kaitlin Mason (b) (4)	15 Feb 2021 16:40:12
	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

US3742357

Folder: Covid-19 Assessment 28 Dec 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	15 Feb 2021 16:40:12
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	15 Feb 2021 16:40:12
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	15 Feb 2021 16:40:12
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)'	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:23:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:27:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:19:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:25:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 17:23:04

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
User accepted default value 'Day 3 (Day 3)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Per GCL Lab Recon: Re-query: Saliva: Please confirm the correct date for Day 3 in query response, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 08:08:43
Query 'Per GCL Lab Recon: Re-query: Saliva: Please confirm the correct date for Day 3 in query response, thank you.' answered with 'confirmed date is correct ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:44:41
User opened query 'Per GCL Lab Recon: Re-query: Saliva: Please confirm the correct date for Day 3 in query response, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 04:42:52
Query 'Per GCL Lab Recon: Re-query: Saliva: Please confirm the correct date for Day 3 in query response , thank you.' canceled (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 04:42:27
User opened query 'Per GCL Lab Recon: Re-query: Saliva: Please confirm the correct date for Day 3 in query response , thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 04:41:56
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 11DEC2020 for Day 3 is recorded in EDC, however sample is reported with 10DEC2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 04:29:20
Query 'Per GCL Lab Recon: Saliva: Sample dated 11DEC2020 for Day 3 is recorded in EDC, however sample is reported with 10DEC2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' answered with 'UPDATED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:00:50
User entered '10 Dec 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:00:45
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 11DEC2020 for Day 3 is recorded in EDC, however sample is reported with 10DEC2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 06:47:48

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '11 Dec 2020'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
User accepted default value 'Day 5 (Day 5)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'NA (COVID-19 Negative) (NA)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 13:43:15

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
User accepted default value 'Day 7 (Day 7)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'NA (COVID-19 Negative) (NA)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
User accepted default value 'Day 9 (Day 9)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'NA (COVID-19 Negative) (NA)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
User accepted default value 'Day 14 (Day 14)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'NA (COVID-19 Negative) (NA)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 13:43:15

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
User accepted default value 'Day 21 (Day 21)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15
	(b) (4)	

US3742357

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'NA (COVID-19 Negative) (NA)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15

US3742357

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 13:43:15

US3742357

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
User accepted default value 'Day 28 (Day 28)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15
	(b) (4)	

US3742357

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'NA (COVID-19 Negative) (NA)'	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15

US3742357

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:43:15

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered '30 Dec 2020'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered '01 Jan 2021'	Kaitlin Mason (b) (4)	02 Feb 2021 21:03:27
	(b) (4)	

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered '03 Jan 2021'	Kaitlin Mason (b) (4)	02 Feb 2021 21:03:27
	(b) (4)	

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered '05 Jan 2021'	Kaitlin Mason (b) (4)	02 Feb 2021 21:03:27
	(b) (4)	

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered '10 Jan 2021'	Kaitlin Mason (b) (4)	02 Feb 2021 21:03:27
	(b) (4)	

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered '17 Jan 2021'	Kaitlin Mason (b) (4)	02 Feb 2021 21:03:27
	(b) (4)	

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:27:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:27:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Un-verified.	Kaitlin Mason (b) (4)	20 Feb 2021 16:38:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 16:38:05
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered 'No (N)'	Kaitlin Mason (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:26:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Un-verified.	Kaitlin Mason (b) (4)	20 Feb 2021 16:38:05
User entered '03 Feb 2021' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 16:38:05
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:26:38
User entered empty.	Kaitlin Mason (b) (4)	02 Feb 2021 21:03:27

US3742357

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:23
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:47:36

US3742357

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:23
User entered '08 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:47:36

US3742357

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:23
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:47:36

US3742357

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:24
User entered 'SICKD1'	System	08 Dec 2020 20:47:36

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:36
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:36
User entered '08 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:36
User entered '10:10'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User entered '08 Dec 2020 10:10'	System	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:36
User entered '187.5' cm	Sherry McCammon (b) (4)	08 Dec 2020 20:48:50
DataPoint set to visible.	(b) (4) System	08 Dec 2020 20:47:36

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:36
User entered '239.4' lb	Sherry McCammon (b) (4)	08 Dec 2020 20:48:50
DataPoint set to visible.	(b) (4) System	08 Dec 2020 20:47:36

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:36
User entered '98.5' F	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:36
User entered 'Oral (Oral)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:36
User entered empty.	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:36
User entered '65'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User entered 'bpm'	System	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:36
User entered '14'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User entered 'breaths/min'	System	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:36
User entered '136'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User entered 'mmHg'	System	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:36
User entered '88'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57
User entered 'mmHg'	System	08 Dec 2020 20:48:50

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:42:57

US3742357

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:56
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:49:30

US3742357

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:28:56
User entered '08 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:49:30

US3742357

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:27:48

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:29:06
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:49:45

US3742357

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:43:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:29:06
User entered '08 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:49:45

US3742357

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:24:31
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:27:00

US3742357

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 28-DEC-2020 is reported under Illness Visit Day 1 in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Please verify date of sample collection as it is prior to study entry date. Else clarify.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 11:08:57
' (Site from DM).		
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 and 01JAN2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 06:30:35
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:24:31
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 28-DEC-2020 is reported under Illness Visit Day 1 in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Please verify date of sample collection as it is prior to study entry date. Else clarify.	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:05:05
' answered with 'UPDATED' (Site from DM).		

US3742357

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 and 01JAN2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'UPDATED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 21:03:55
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 28-DEC-2020 is reported under Illness Visit Day 1 in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Please verify date of sample collection as it is prior to study entry date. Else clarify.	(b) (4), (b) (6) (b) (4)	06 Jan 2021 09:10:55
' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 and 01JAN2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4)	06 Jan 2021 06:22:56
User entered '28 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:27:00

US3742357

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:24:31
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:27:00

US3742357

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	29 Dec 2020 18:27:00

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:25:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:25:53
User entered '28 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:25:53
User entered '14:15'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Dec 2020 14:15'	System	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:25:53
User entered '188.0' cm	Sherry McCammon (b) (4)	29 Dec 2020 18:28:41
DataPoint set to visible.	(b) (4) System	29 Dec 2020 18:27:00

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:25:53
User entered '243.8' lb	Sherry McCammon (b) (4)	29 Dec 2020 18:28:41
DataPoint set to visible.	(b) (4) System	29 Dec 2020 18:27:00

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:25:53
User entered '98.0' F	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:25:53
User entered 'Oral (Oral)'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:25:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:25:53
User entered '76'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:25:53
User entered '16'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:25:53
User entered '124'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:25:53
User entered '86'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Dec 2020 18:28:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:26:01
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:30:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:26:01
User entered '28 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:30:41

US3742357

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:27:48

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Sample dated 03FEB2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 10:24:44
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Sample dated 03FEB2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details, thank you. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Feb 2021 16:38:23
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Sample dated 03FEB2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details, thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 06:30:03
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03FEB2021 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 06:30:03
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03FEB2021 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:53:14

US3742357

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:27:48

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03FEB2021 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 05:25:45
	(b) (4), (b) (6)	04 Feb 2021 19:26:07
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	29 Dec 2020 18:30:27
	(b) (4)	

US3742357

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Per GCL Lab Recon: SARS-CoV2: Sample dated 03 FEB 2021 is reported under Convalescent Visit Day 28 in PPD GCL, however the same is missing in EDC. Please update the missing SARS sample details in EDC by entering data in Convalescence visit day 28 form. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 10:24:52
Query 'Per GCL Lab Recon: SARS-CoV2: Sample dated 03 FEB 2021 is reported under Convalescent Visit Day 28 in PPD GCL, however the same is missing in EDC. Please update the missing SARS sample details in EDC by entering data in Convalescence visit day 28 form. Thank you.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:53:19
User opened query 'Per GCL Lab Recon: SARS-CoV2: Sample dated 03 FEB 2021 is reported under Convalescent Visit Day 28 in PPD GCL, however the same is missing in EDC. Please update the missing SARS sample details in EDC by entering data in Convalescence visit day 28 form. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 16:25:43
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:26:07
User entered '28 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:30:27

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Yes (Y)'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:50:13

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '03 Feb 2021'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:50:13

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Clinic (Clinic)'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:50:13

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:28
User entered 'SICKD28'	System	15 Feb 2021 16:50:13

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Yes (Y)'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '03 Feb 2021'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '13:06'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
User entered '03 Feb 2021 13:06'	System	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '187.8' cm	(b) (4) Kaitlin Mason (b) (4)	15 Feb 2021 16:52:57
DataPoint set to visible.	(b) (4) System	15 Feb 2021 16:50:13

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '241' lb	(b) (4) Kaitlin Mason (b) (4)	15 Feb 2021 16:52:57
DataPoint set to visible.	(b) (4) System	15 Feb 2021 16:50:13

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '98.3' F	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Oral (Oral)'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '60'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
User entered 'bpm'	System	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '16'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
User entered 'breaths/min'	System	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '124'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
User entered 'mmHg'	System	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:30:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '81'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40
User entered 'mmHg'	System	15 Feb 2021 16:50:03

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:40

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:46
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:31:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Yes (Y)'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:48:59

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:46
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:31:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '03 Feb 2021'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:48:59

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:27:48

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:52
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:32:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Yes (Y)'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:48:46

US3742357

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:27:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:52
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:32:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '03 Feb 2021'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	15 Feb 2021 16:48:46

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:00:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Yes (Y)'	(b) (4)	20 Jan 2021 14:34:44
	(b) (4), (b) (6)	

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:00:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:34:44

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:00:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:34:44

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 14:34:44

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:27:48

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:33
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:48:23
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:49:36
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 16:49:36
User entered '20 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:49:36
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:36:19

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:27:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:41:06
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:21:46

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:27:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:36:19

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:27:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:33
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:48:23
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:49:36
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:49:36
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:41:06
User entered empty. WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:21:46

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:27:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:36:19

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:27:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:36:19

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:27:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 14:57:26
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	20 Jan 2021 14:36:19

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:27:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 14:57:26
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	20 Jan 2021 14:36:19

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:27:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:36:19

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:27:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
User entered empty.	System	20 Jan 2021 14:36:19

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:27:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
User entered empty.	System	20 Jan 2021 14:36:19

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:35:39

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:35:39

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '09:00'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:35:39

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
User entered '20 Jan 2021 09:00'	System	20 Jan 2021 14:35:39

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:27:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:35:58

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:27:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:35:58

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:27:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '09:04'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:35:58

US3742357

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:27:48

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:08
User entered '20 Jan 2021 09:04'	System	20 Jan 2021 14:35:58

US3742357

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:27:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:22
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:40:03

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:30:56
User closed query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:10:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 16:00:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 16:00:00
Query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'data was updated and corresponds with ConMed entry.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:44:01
Data point term sent to Coder	System	19 Nov 2020 15:43:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 15:43:19
Coding entries removed.	(b) (4), (b) (6)	19 Nov 2020 15:43:19
User entered 'generalized BODY ACHES' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 15:43:19
User opened query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:34:44
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:28

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 12:42:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 12:42:47
Data point term sent to Coder	System	13 Oct 2020 12:41:33
User entered 'BODY ACHES'	Sherry McCammon (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Per DM CLR-RQ: Site's response noted. However, this AE started after the 7-day post vaccination period for collecting solicited events and this AE is considered as Unsolicited event. Please review and update response to NO as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:24:00
Query 'Per DM CLR-RQ: Site's response noted. However, this AE started after the 7-day post vaccination period for collecting solicited events and this AE is considered as Unsolicited event. Please review and update response to NO as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	29 Jan 2021 13:31:28
DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	29 Jan 2021 13:31:22
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	29 Jan 2021 13:31:22
User opened query 'Per DM CLR-RQ: Site's response noted. However, this AE started after the 7-day post vaccination period for collecting solicited events and this AE is considered as Unsolicited event. Please review and update response to NO as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 00:18:20
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:11:36
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' answered with 'field is correct, this is a solicited adverse reaction.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:47:41

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:34:50
	(b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
DataPoint Un-verified.	Sherry McCammon (b) (4)	08 Dec 2020 20:43:50
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:43:50
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered '6 Oct 2020'	Sherry McCammon (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User entered empty.	System	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
DataPoint Un-verified.	Sherry McCammon (b) (4)	08 Dec 2020 20:43:50
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:43:50
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered '6 Oct 2020'	Sherry McCammon (b) (4)	13 Oct 2020 12:41:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User entered empty.	System	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 12:41:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 12:41:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:41
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 12:41:26
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 12:41:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 12:41:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:41
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 12:41:26
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered 'None (NONE)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered 'l'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered '0'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:28
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User entered '0'	System	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04
User entered '0'	System	13 Oct 2020 12:41:26

US3742357

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:27:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:27:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:27:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Laceration of finger - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 23:41:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 23:41:28
Data point term sent to Coder	System	20 Oct 2020 16:44:23
User entered 'right middle finger laceration'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

US3742357

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:27:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:27:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:27:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

US3742357

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:27:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered '13 Oct 2020'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:27:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:27:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User entered empty.	System	20 Oct 2020 16:43:26

US3742357

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:30:56
DataPoint Un-verified.	Hassan Haji (b) (4)	06 Nov 2020 18:46:09
User entered 'No (N)' reason for change: New Information	(b) (4) Hassan Haji (b) (4)	06 Nov 2020 18:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 12:58:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 12:58:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	26 Oct 2020 12:58:07
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 16:43:26
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
DataPoint Un-verified.	Sherry McCammon (b) (4)	08 Dec 2020 20:44:43
User entered '02 Nov 2020' reason for change: New Information	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:44:43
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:30:56
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 19:50:08
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	06 Nov 2020 18:46:46
DataPoint Un-verified.	Hassan Haji (b) (4) (b) (4)	06 Nov 2020 18:46:46
User entered '2 Nov 2020' reason for change: New Information	Hassan Haji (b) (4) (b) (4)	06 Nov 2020 18:46:46
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'entered ' (Site from System).	Hassan Haji (b) (4) (b) (4)	06 Nov 2020 18:46:15
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	06 Nov 2020 18:46:09
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	06 Nov 2020 18:46:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User entered empty.	System	20 Oct 2020 16:43:26

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Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 12:58:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 12:58:07
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	26 Oct 2020 12:58:07
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 16:43:26
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:27:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered 'None (NONE)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	29 Dec 2020 18:14:12
User entered '1' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	29 Dec 2020 18:14:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	26 Oct 2020 12:58:07
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Oct 2020 16:43:26
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 18:25:56
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' answered with 'CORRECTED' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:14:20
DataPoint Un-verified.	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:14:12
User entered '0' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:14:12
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 14:20:30
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	26 Oct 2020 12:58:07
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:30:56
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 18:46:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 18:46:09
DataPoint Un-verified.	Hassan Haji (b) (4) (b) (4)	06 Nov 2020 18:46:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Hassan Haji (b) (4) (b) (4)	06 Nov 2020 18:46:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:42:45
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 16:43:26
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:43:26

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Form: Adverse Events (2)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User entered '0'	System	26 Oct 2020 12:58:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:27:48

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09
User entered 'I'	System	20 Oct 2020 16:43:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:09

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Folder: Adverse Events

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 15:26:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 15:26:06
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection NOS - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 20:20:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 20:20:45
Data point term sent to Coder	System	07 Dec 2020 20:19:56
User entered 'viral illness unspecified'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 20:45:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 20:45:56
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:45:56
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:19:15
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 20:45:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 20:45:56
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:45:56
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:19:15
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 20:45:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 20:45:56
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:45:56
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:19:15
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered '05 Dec 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:45:56
User entered '5 Dec 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User entered empty.	System	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	29 Dec 2020 18:15:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	29 Dec 2020 18:15:22
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 17:31:05
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 20:45:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 20:45:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:45:56
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:19:15
User entered empty.	Hassan Haji (b) (4)	07 Dec 2020 20:19:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	29 Dec 2020 18:15:22
User entered '13 Dec 2020' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	29 Dec 2020 18:15:22
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User entered empty.	System	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 20:45:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 20:45:56
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:45:56
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:19:15
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 20:45:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 20:45:56
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:45:56
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:19:15
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 20:45:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 20:45:56
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:45:56
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:19:15
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 20:45:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 20:45:56
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:45:56
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:19:15
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Dec 2020 20:45:56
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Dec 2020 20:19:15
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered '1' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 20:45:56
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	29 Dec 2020 18:15:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	29 Dec 2020 18:15:22
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:31:05
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 20:19:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User entered '0'	System	08 Dec 2020 20:45:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14
User entered '0'	System	08 Dec 2020 20:45:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:27:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:14

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered	(b) (4)	08 Jan 2021 17:34:16
'USA-US127-2021-mRNA-1273-P301000004'	System	08 Jan 2021 17:34:16
User entered 'New'	(b) (4), (b) (6)	08 Jan 2021 17:34:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Query 'PV Query Urgent: Did the subject experience an event of symptomatic positive Covid-19? If yes, please update event term to Covid-19. If no, please change answer to 'No'.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:29:22
User opened query 'PV Query Urgent: Did the subject experience an event of symptomatic positive Covid-19? If yes, please update event term to Covid-19. If no, please change answer to 'No'.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 21:12:16
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Jan 2021 21:38:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Jan 2021 21:38:45
Data point term sent to Coder	System	07 Jan 2021 21:37:51
Coding entries removed.	(b) (4), (b) (6)	07 Jan 2021 21:36:53
User entered 'Symptomatic COVID-19' reason for change: New Information	(b) (4), (b) (6)	07 Jan 2021 21:36:53
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:20:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:20:36
Data point term sent to Coder	System	29 Dec 2020 18:19:03
User entered 'VIRAL ILLNESS UNSPECIFIED'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Jan 2021 21:55:19
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:45:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:45:21
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	05 Jan 2021 17:45:21
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:18:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Jan 2021 17:45:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:45:21
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	05 Jan 2021 17:45:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Dec 2020 18:18:10
	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Yes (Y)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	07 Jan 2021 21:41:57
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:20:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 18:20:36
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:20:36
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:19:05
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:19:05
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '24 Dec 2020'	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

US3742357

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

US3742357

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Dec 2020 18:18:10

US3742357

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 17:24:44
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	05 Jan 2021 17:46:01
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Dec 2020 18:18:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

US3742357

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:38:55
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' answered with 'UPDATED' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 20:56:16
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	02 Feb 2021 20:56:10
User entered '08 Jan 2021' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 20:56:10
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	02 Feb 2021 20:55:58
User entered '08 Jan 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 20:55:58
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 21:11:21
User entered '28 Dec 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:24:44
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Jan 2021 17:46:01
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	05 Jan 2021 17:46:01
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4) (b) (4)	05 Jan 2021 17:46:01
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Jan 2021 17:45:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Dec 2020'	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating end date to when all symptoms resolved. (per symptom log 09 Jan 2021)' canceled (Site from Safety).	(b) (4), (b) (6)	18 Apr 2021 15:56:33
User opened query 'PV Query: Please consider updating end date to when all symptoms resolved. (per symptom log 09 Jan 2021)' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 21:44:28
User entered empty.	System	29 Dec 2020 18:18:10

US3742357

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

US3742357

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Jan 2021 17:45:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:45:21
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	05 Jan 2021 17:45:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Dec 2020 18:18:10
	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '0'	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

US3742357

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '0'	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '0'	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '0'	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '0'	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '0'	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Jan 2021 17:45:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:45:21
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	05 Jan 2021 17:45:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Dec 2020 18:18:10
User entered empty.	System	29 Dec 2020 18:18:10
	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Jan 2021 17:45:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:45:21
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	05 Jan 2021 17:45:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Dec 2020 18:18:10
User entered empty.	System	29 Dec 2020 18:18:10
	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Jan 2021 17:45:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:45:21
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	05 Jan 2021 17:45:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Dec 2020 18:18:10
User entered empty.	System	29 Dec 2020 18:18:10
	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '0'	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:38:59
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' answered with 'NA' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 20:56:23
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 21:11:50
User entered '1'	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '0'	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:39:02
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'UPDATED' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 20:56:28
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 21:11:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 17:24:44
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:45:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:45:21
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	05 Jan 2021 17:45:21
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:18:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	29 Dec 2020 18:18:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	05 Jan 2021 17:45:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:27:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Jan 2021 21:55:19
User entered '0'	System	05 Jan 2021 17:45:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bartonella infections, PT: Cat scratch disease, LLT: Cat scratch disease - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 13:43:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 13:43:08
Data point term sent to Coder	System	23 Apr 2021 13:34:16
User entered 'Cat Scratch Disease'	(b) (4), (b) (6)	23 Apr 2021 13:33:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '03 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 13:33:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '09 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 13:33:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:03
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 13:33:21

US3742357

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:27:48

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 13:33:21

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:27:48

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:08
Query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:16:23
User opened query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:32:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:29:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:46:41

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Oct 2020 04:12:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:12:39
Data point term sent to Coder	System	24 Oct 2020 19:12:14
Coding entries removed.	(b) (4), (b) (6)	24 Oct 2020 19:11:51
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 13:48:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 13:48:57
Data point term sent to Coder	System	18 Sep 2020 13:47:59
User entered 'ZINC'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:47:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 19:42:21
User closed query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 16:46:26
Query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' answered with 'error corrected' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 19:12:07
DataPoint Un-verified.	(b) (4), (b) (6)	24 Oct 2020 19:11:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Oct 2020 19:11:51
User opened query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:50:30
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'No (N)'	Sherry McCammon (b) (4)	18 Sep 2020 13:47:26
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 19:42:21
DataPoint Un-verified.	(b) (4), (b) (6)	24 Oct 2020 19:11:51
User entered 'Prophylaxis SUPPLEMENT' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Oct 2020 19:11:51
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'SUPPLEMENT'	Sherry McCammon (b) (4)	18 Sep 2020 13:47:26
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:26:51
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 20:33:33
Signature has been broken.	(b) (4) Sherry McCammon (b) (4)	08 Apr 2021 19:36:50
User signature succeeded.	(b) (4) Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered '50'	Sherry McCammon (b) (4)	18 Sep 2020 13:47:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'mg (mg)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:47:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 20:33:33
	(b) (4)	
Signature has been broken.	Sherry McCammon (b) (4)	08 Apr 2021 19:48:43
	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	18 Sep 2020 13:47:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'once daily (QD)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:47:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 20:33:33
	(b) (4)	
Signature has been broken.	Sherry McCammon (b) (4)	08 Apr 2021 19:48:25
	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	18 Sep 2020 13:47:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:47:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:47:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'UN Sep 2019'	Sherry McCammon (b) (4)	18 Sep 2020 13:47:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered '0'	Sherry McCammon (b) (4)	18 Sep 2020 13:47:26
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:47:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:47:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:47:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 13:47:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 13:47:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 13:47:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Oct 2020 19:13:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 19:13:31
Data point term sent to Coder	System	24 Oct 2020 19:13:15
Coding entries removed.	(b) (4), (b) (6)	24 Oct 2020 19:12:52
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 13:50:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 13:50:03
Data point term sent to Coder	System	18 Sep 2020 13:49:08
User entered 'VITAMIN C'	Sherry McCammon (b) (4)	18 Sep 2020 13:48:56

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 19:42:21
User closed query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 16:46:29
Query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' answered with 'Corrected' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 19:13:02
DataPoint Un-verified.	(b) (4), (b) (6)	24 Oct 2020 19:12:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Oct 2020 19:12:52
User opened query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:50:37
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'No (N)'	Sherry McCammon (b) (4)	18 Sep 2020 13:48:56
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 19:42:21
DataPoint Un-verified.	(b) (4), (b) (6)	24 Oct 2020 19:12:52
User entered 'Prophylaxis SUPPLEMENT' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Oct 2020 19:12:52
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'SUPPLEMENT'	Sherry McCammon (b) (4)	18 Sep 2020 13:48:56
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 13:51:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 13:51:33
User entered '1,000' reason for change: Data Entry Error	Sherry McCammon (b) (4)	18 Sep 2020 13:51:33
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 13:48:56
User entered empty.	Sherry McCammon (b) (4)	18 Sep 2020 13:48:56
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:08:13
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 20:33:33
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	08 Apr 2021 19:28:30
Signature has been broken.	(b) (4)	
	Sherry McCammon (b) (4)	08 Apr 2021 19:28:30
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	08 Apr 2021 19:28:30
User signature succeeded.	(b) (4)	
	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 14:11:18
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'PER PARTICIPANT REPORT ' (Site from DM).	Kaitlin Mason (b) (4)	02 Feb 2021 20:57:31
	(b) (4)	
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 06:43:06
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:30:37
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 14:36:19
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 14:36:19
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	18 Sep 2020 13:48:56
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:30:37
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 15:12:32
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:37:34
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 14:36:19
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 14:36:19
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:21:43
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'UNITS'	Sherry McCammon (b) (4)	18 Sep 2020 13:48:56
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'once daily (QD)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:48:56

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:48:56

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:48:56

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:48:56

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	18 Sep 2020 13:50:32
User entered 'UN Sep 2019' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:50:32
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	18 Sep 2020 13:48:56
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:48:56

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered '0'	Sherry McCammon (b) (4)	18 Sep 2020 13:48:56
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:48:56

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:48:56

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:48:56

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 13:48:56

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 13:48:56

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 13:48:56

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 15:11:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 15:11:48
Data point term sent to Coder	System	18 Sep 2020 13:50:10
User entered 'PAMTOPRAZOL'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'GERD'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:30:37
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 15:14:42
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'entered ' (Site from DM).	Hassan Haji (b) (4)	06 Nov 2020 18:40:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 18:40:46
User entered '40' reason for change: New Information	System	06 Nov 2020 18:40:46
User opened query 'Data is required. Please complete.' (Site from System).	Hassan Haji (b) (4)	06 Nov 2020 18:40:46
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:57:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 14:57:56
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:22:49
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered '2'	Sherry McCammon (b) (4)	18 Sep 2020 13:50:07
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:30:37
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 14:57:56
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 14:57:56
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'tablet (TABLET)'	Sherry McCammon (b) (4)	18 Sep 2020 13:50:07
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:30:37
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 14:57:56
User entered 'twice daily (BID)' reason for change:	(b) (4), (b) (6)	05 Nov 2020 14:57:56
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'as needed (PRN)'	Sherry McCammon (b) (4)	18 Sep 2020 13:50:07
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'UN UNK 2019'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered '0'	Sherry McCammon (b) (4)	18 Sep 2020 13:50:07
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 14:57:56
User entered empty.	System	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 14:57:56
User entered empty.	System	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 14:57:56
User entered empty.	System	18 Sep 2020 13:50:07

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 20:42:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	08 Dec 2020 20:42:54
Data point term sent to Coder Coding entries removed.	System Sherry McCammon (b) (4)	08 Dec 2020 20:32:16 08 Dec 2020 20:32:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 18:20:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	12 Oct 2020 18:20:28
Data point term sent to Coder User entered 'naproxen'	System Sherry McCammon (b) (4)	12 Oct 2020 18:19:49 12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
DataPoint Un-verified.	Sherry McCammon (b) (4)	08 Dec 2020 20:32:11
User entered 'Generalized BODY ACHES' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	08 Dec 2020 20:32:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'body aches'	Sherry McCammon (b) (4)	12 Oct 2020 18:19:12
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered '500'	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'mg (mg)'	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered empty.	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'once (ONCE)'	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered empty.	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered empty.	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
DataPoint Un-verified.	Sherry McCammon (b) (4)	07 Dec 2020 14:52:40
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	07 Dec 2020 14:52:40
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered '6 Oct 2020'	Sherry McCammon (b) (4)	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered '0'	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
DataPoint Un-verified.	Sherry McCammon (b) (4)	07 Dec 2020 14:52:40
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	07 Dec 2020 14:52:40
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered '6 Oct 2020'	Sherry McCammon (b) (4)	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 20:38:05
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. ' answered with 'Corrected' (Site from DM).	Sherry McCammon (b) (4)	07 Dec 2020 14:52:29
DataPoint Un-verified.	Sherry McCammon (b) (4)	07 Dec 2020 14:52:13
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Dec 2020 14:52:13
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 14:48:20
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:30:37
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User entered empty.	System	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User entered empty.	System	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:46
User entered empty.	System	12 Oct 2020 18:19:12

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALOXIN, PRODUCTSYNONYM: CEPHALOXIN [CEPHALOXIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 11:53:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 11:53:35
Data point term sent to Coder	System	20 Oct 2020 16:41:17
User entered 'cephalexin'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered 'prophylaxis infection'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered '500'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered 'mg (mg)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered 'three times daily (TID)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered '15 Oct 2020'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Oct 2020 19:14:22
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered '21 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Oct 2020 19:14:22
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:42:21
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User entered '3'	System	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User entered '1'	System	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:48
User entered '804 (804)'	System	20 Oct 2020 16:40:32

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #9 and #10. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 08:35:31
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #9 and #10. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' answered with 'updated' (Site from DM).	Sherry McCammon (b) (4)	16 Mar 2021 17:04:30
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #9 and #10. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 15:19:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: NYQUIL SEVERE COLD & FLU - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Dec 2020 16:38:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:38:49
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 17:30:31

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	08 Dec 2020 20:41:28
User entered 'Nyquil Liquid- acetaminophen 650 mg, Sherry McCammon (b) (4)		08 Dec 2020 20:41:16
dextromethorphan 20 mg , doxylamine succinate 12.5 (b) (4)		
mg, phenylephrine 10 mg'		

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
User entered 'unspecified viral illness'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
User entered '30'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
User entered 'mL (mL)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
User entered empty.	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
User entered 'as needed (PRN)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
User entered empty.	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
User entered empty.	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
User entered '06 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
User entered '0'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 19:16:36
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	15 Feb 2021 16:38:30
DataPoint Un-verified.	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	15 Feb 2021 16:38:25
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 04:57:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 17:30:31
	Sherry McCammon (b) (4)	08 Dec 2020 20:41:16
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:41
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 20:33:33
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Sherry McCammon (b) (4)	16 Mar 2021 17:04:19
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Sherry McCammon (b) (4)	16 Mar 2021 17:04:19
User signature succeeded.	(b) (4)	
DataPoint Un-verified.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '24 Jan 2021' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Kaitlin Mason (b) (4)	15 Feb 2021 16:38:25
User entered empty.	(b) (4)	
	Kaitlin Mason (b) (4)	15 Feb 2021 16:38:25
	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:30:31
	(b) (4)	
	Sherry McCammon (b) (4)	08 Dec 2020 20:41:16
	(b) (4)	

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:31
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User entered empty.	System	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User entered empty.	System	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:51
User entered empty.	System	08 Dec 2020 20:41:16

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: PREPARATIONS WITH SALICYLIC ACID DERIVATIVES, PRODUCT: MENTHOL;METHYL SALICYLATE, PRODUCTSYNONYM: SALONPAS [MENTHOL;METHYL SALICYLATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 14:34:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 14:34:16
Data point term sent to Coder	System	15 Dec 2020 13:59:31
User entered 'MENTHOL 10%, METHYL SALICYLATE 30 %'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)'	Sherry McCammon (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'VIRAL ILLNESS UNSPECIFIED'	Sherry McCammon (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'l'	Sherry McCammon (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'APPLICATION'	Sherry McCammon (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'as needed (PRN)'	Sherry McCammon (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'Topical (TOPICAL)'	Sherry McCammon (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered empty.	Sherry McCammon (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '09 Dec 2020'	(b) (4) Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '0'	Sherry McCammon (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)'	Sherry McCammon (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '10 Dec 2020'	(b) (4) Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:02:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered 'No (N)'	Sherry McCammon (b) (4)	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
User entered empty.	System	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
User entered empty.	System	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:26:53
User entered empty.	System	15 Dec 2020 13:59:06

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 13:31:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 13:31:57
Data point term sent to Coder	System	23 Apr 2021 13:29:08
User entered 'Azithromycin'	(b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Cat scratch disease'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '500'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 13:28:26

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 13:31:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 13:31:57
Data point term sent to Coder	System	23 Apr 2021 13:30:08
User entered 'Azithromycin'	(b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Cat Scratch Disease'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '250'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:52
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:27:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 13:29:44

US3742357

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:27:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:05:44
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:41:06
User entered 'No (N)'	Sherry McCammon (b) (4)	12 Mar 2021 18:37:33

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'USA-US127-2021-MRNA-1273-P301000004'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'Karen'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'Kotloff'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered '685 W. Baltimore Street, HSF 480'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'Baltimore'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered '21201'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'US'	System	08 Jan 2021 17:37:51

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
	(b) (4)	
User entered '2'	System	11 Feb 2021 21:40:20
User entered '1'	System	08 Jan 2021 17:37:51

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'USA-US127-2021-MRNA-1273-P301000004'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'Karen'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'Kotloff'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered '685 W. Baltimore Street, HSF 480'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'Baltimore'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered '21201'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'US'	System	08 Jan 2021 17:37:51

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
	(b) (4)	
User entered '2'	System	11 Feb 2021 21:40:20
User entered '1'	System	08 Jan 2021 17:37:51

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:27:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '08/Jan/2021 12:37'	(b) (4) System	08 Jan 2021 17:37:51

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:27:48

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'I'	(b) (4), (b) (6)	08 Jan 2021 17:37:51

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'USA-US127-2021-MRNA-1273-P301000004'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'No (N)'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'Karen'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'Kotloff'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered '685 W. Baltimore Street, HSF 480'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'Baltimore'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered '21201'	System	08 Jan 2021 17:34:16

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:37:56
User entered 'US'	System	08 Jan 2021 17:37:51

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:27:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
	(b) (4)	
User entered '2'	System	11 Feb 2021 21:40:20
User entered '1'	System	08 Jan 2021 17:37:51

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:27:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
User entered '11/Feb/2021 15:40'	(b) (4) System	11 Feb 2021 21:40:20

US3742357

Folder: SAE USA-US127-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:27:48

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:23:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:07:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:41:39
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 21:40:20