

US3682018 (Prod: UCLA Vine Street Clinic - (CRS))

Generated By: KC Joubran

Generated On: 11 Aug 2021 23:02:48

All time stamps listed in this document are displayed in GMT

US3682018

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 20:38:26

Generated On: 11 Aug 2021 23:02:48

[Participant ID](#)

US3682018

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

US3682018

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 23:10:18

Generated On: 11 Aug 2021 23:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 23:10:18

Generated On: 11 Aug 2021 23:02:48

Date of Birth (MMM yyyy)	(b) (6) 1979
Age	40
Age Units	YEARS
Age (Derived)	40
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	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	True

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 23:10:18

Generated On: 11 Aug 2021 23:02:48

Date of Informed Consent (<i>dd MMM yyyy</i>)	26 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input 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) 19 Feb 2021 23:10:18

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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) 19 Feb 2021 23:10:18

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Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 23:10:18

Generated On: 11 Aug 2021 23:02:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:05 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 13:05
Height (<i>xxx.x</i>)	74 in
Weight (<i>xxx.x</i>)	91 kg
BMI (<i>xxx.x</i>)	25.75790 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 23:10:18

Generated On: 11 Aug 2021 23:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 23:10:18

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 23:10:18

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 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) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 108508

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) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

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) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

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)	26 AUG 2020
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 13:05
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

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)	26 AUG 2020
Time of assessment (00:00-23:59)	14:31 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 14:31
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)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 13:56 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 13:56

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) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 AUG 2020

Collection time (00:00-23:59)

13:48 (24 HR)

Collection date and time (derived)

26 AUG 2020 13:48

US3682018

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:51	26 AUG 2020 13:51
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

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: 11 Aug 2021 23:02:48

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 14:27

PC Open Date & Time

26 AUG 2020 14:16

PC Close Date & Time

26 AUG 2020 16:46

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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

97.0 °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

27 AUG 2020 10:18

PC Open Date & Time

26 AUG 2020 17:41

PC Close Date & Time

27 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 11:31

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 06:49

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

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

97.0 °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

30 AUG 2020 10:11

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 11:35

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

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

97.3 °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

01 SEP 2020 06:01

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 23:42

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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

26 AUG 2020 14:27

PC Open Date & Time

26 AUG 2020 14:16

PC Close Date & Time

26 AUG 2020 16:46

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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 - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 10:19

PC Open Date & Time

26 AUG 2020 17:41

PC Close Date & Time

27 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

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

28 AUG 2020 11:32

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

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

29 AUG 2020 06:49

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

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

30 AUG 2020 10:11

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

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

31 AUG 2020 11:36

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

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

01 SEP 2020 06:01

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

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

01 SEP 2020 23:42

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 14:28
PC Open Date & Time	26 AUG 2020 14:16
PC Close Date & Time	26 AUG 2020 16:46

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 10:20
PC Open Date & Time	26 AUG 2020 17:41
PC Close Date & Time	27 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

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 ☒

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 11:32
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

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 ☒

PRODUCTION RELEASE (v12.003

43 of 3030

EAB) (1725)

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 06:50
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

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 ☒

PRODUCTION RELEASE (v12.003

45 of 3030

EAB) (1725)

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 10:12
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

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 ☒

PRODUCTION RELEASE (v12.003

47 of 3030

EAB) (1725)

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 11:36
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

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 ☒

PRODUCTION RELEASE (v12.003

49 of 3030

EAB) (1725)

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 06:02
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

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 ☒

PRODUCTION RELEASE (v12.003

51 of 3030

EAB) (1725)

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 23:43
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3682018

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:10:18

Generated On: 11 Aug 2021 23:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682018

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:10:18

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:10:18

Generated On: 11 Aug 2021 23:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682018

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:10:18

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 21:58:33

Generated On: 11 Aug 2021 23:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682018

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:10:18

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:58:34

Generated On: 11 Aug 2021 23:02:48

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)	23 SEP 2020
Time of assessment (00:00-23:59)	12:56 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 12:56
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)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:58:34

Generated On: 11 Aug 2021 23:02:48

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	13:59 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 13:59
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3682018

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3682018

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 13:28 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 13:28

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

What was the frequency of the study treatment dosing? ONCE

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

US3682018

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

13:08 (24 HR)

Collection date and time (derived)

23 SEP 2020 13:08

US3682018

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:11	23 SEP 2020 13:11
Nasopharyngeal Swab 2	No		

US3682018

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 14:01

PC Open Date & Time

23 SEP 2020 13:48

PC Close Date & Time

23 SEP 2020 16:18

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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 97.4 °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	23 SEP 2020 23:41
PC Open Date & Time	23 SEP 2020 17:13
PC Close Date & Time	24 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 06:22

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 10:27

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 09:35

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

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

97.7 °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

29 SEP 2020 00:19

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

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

97.3 °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

30 SEP 2020 11:11

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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

23 SEP 2020 14:02

PC Open Date & Time

23 SEP 2020 13:48

PC Close Date & Time

23 SEP 2020 16:18

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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 - **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

23 SEP 2020 23:43

PC Open Date & Time

23 SEP 2020 17:13

PC Close Date & Time

24 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

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

25 SEP 2020 06:22

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

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

26 SEP 2020 10:27

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

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

27 SEP 2020 09:35

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

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 ☐

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

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

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

29 SEP 2020 00:19

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

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

30 SEP 2020 11:14

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 14:02
PC Open Date & Time	23 SEP 2020 13:48
PC Close Date & Time	23 SEP 2020 16:18

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 23:44
PC Open Date & Time	23 SEP 2020 17:13
PC Close Date & Time	24 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

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 ☒

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 06:23
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

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 ☒

PRODUCTION RELEASE (v12.003

89 of 3030

EAB) (1725)

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 10:28
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

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 ☒

PRODUCTION RELEASE (v12.003

91 of 3030

EAB) (1725)

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 09:36
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

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 ☐

PRODUCTION RELEASE (v12.003

93 of 3030

EAB) (1725)

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

Yes ☐

PC Time stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

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 ☒

PRODUCTION RELEASE (v12.003

95 of 3030

EAB) (1725)

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 00:20
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

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 ☒

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 11:14
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3682018

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:10:18

Generated On: 11 Aug 2021 23:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682018

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:10:18

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682018

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682018

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:57:52

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:58:34

Generated On: 11 Aug 2021 23:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:58:34

Generated On: 11 Aug 2021 23:02:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 OCT 2020
Time of assessment (00:00-23:59)	15:27 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 15:27
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682018

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:58:34

Generated On: 11 Aug 2021 23:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3682018

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:58:34

Generated On: 11 Aug 2021 23:02:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 OCT 2020

Collection time (00:00-23:59)

15:51 (24 HR)

Collection date and time (derived)

20 OCT 2020 15:51

US3682018

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:58:34

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 17:55:17

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 14:45:09

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 00:01:41

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 00:11:43

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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	27 NOV 2020 00:02:28
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 00:04:26

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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	11 DEC 2020 00:35:02
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	20 DEC 2020 12:08:17
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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	26 DEC 2020 09:49:07
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 00:04:34

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 16:54:54

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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	18 JAN 2021 17:59:26
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 12:58:38

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	29 JAN 2021 09:21:50
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

08 FEB 2021 12:29:06

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

12 FEB 2021 00:11:15

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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	19 FEB 2021 00:06:04
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 13:31:57

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

07 MAR 2021 12:01:10

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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	14 MAR 2021 15:29:17
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

19 MAR 2021 00:35:11

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

26 MAR 2021 00:02:27

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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	02 APR 2021 17:17:49
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

09 APR 2021 00:02:20

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

Date and time of submission

19 APR 2021 17:59:30

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 22:14:00

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 APR 2021 00:03:34
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐ Yes ☐

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

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

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

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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°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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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°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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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="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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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="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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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°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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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°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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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="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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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="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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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="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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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="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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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°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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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="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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 <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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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

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 ☐

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3682018

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 23:02:48

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
No		28 FEB 2021 13:31:41

US3682018

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:09:15

Generated On: 11 Aug 2021 23:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682018

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:09:15

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682018

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682018

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682018

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:22 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 13:22
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682018

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3682018

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 MAR 2021

Collection time (00:00-23:59)

13:38 (24 HR)

Collection date and time (derived)

24 MAR 2021 13:38

US3682018

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682018

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

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

US3682018

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

Date of Contact	5 FEB 2021
Time of Contact	11:57
Date and Time of Contact (derived)	5 FEB 2021 11:57
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" 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>

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

	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"/>

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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 05 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

	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	3 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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

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Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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 05 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

	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 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"/>

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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

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Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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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Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.7 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

	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"/>

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
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 05 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

	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"/>

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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 05 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

	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 FEB 2021	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

	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"/>

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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 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"/>

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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 05 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
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 05 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

	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 05 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

Date of Visit	05 FEB 2021
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	05 FEB 2021
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

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

Date of Contact	10 DEC 2020
Time of Contact	11:30
Date and Time of Contact (derived)	10 DEC 2020 11:30
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" 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>

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 type="checkbox"/>
	Mild	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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"/>

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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	99 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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 type="radio"/>
	Mild	<input checked="" 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 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 10 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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	12 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	101.1 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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EAB) (1725)		

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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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 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 checked="" 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 10 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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	13 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	100.7 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 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 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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 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 checked="" 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"/>

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 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 10 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 10 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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	14 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.6 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 type="checkbox"/>
	Mild	<input checked="" 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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Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" 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 10 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 10 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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	15 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.5 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 type="checkbox"/>
	Mild	<input checked="" 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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Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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 10 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 10 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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	16 DEC 2020
------	-------------

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

O2 Saturation	93 %
---------------	------

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

Temperature	99.3 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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"/>

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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	17 DEC 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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 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 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 10 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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	18 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	95.6 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 10 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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 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 10 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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	19 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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 10 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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	20 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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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US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 10 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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	21 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

	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 10 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 20:38:27

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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 ☐

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

Date of Visit	11 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	11 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 10 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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 16 DEC 2020

End Date 16 DEC 2020

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 10 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Apr 2021 20:38:27

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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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

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

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	13 DEC 2020
Day 5	Yes	15 DEC 2020
Day 7	Yes	17 DEC 2020
Day 9	Yes	19 DEC 2020
Day 14	Yes	24 DEC 2020
Day 21	Yes	31 DEC 2020
Day 28	Yes	08 JAN 2021

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	07 FEB 2021
Day 5	Yes	09 FEB 2021
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)	

US3682018

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 DEC 2020
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	11 DEC 2020 12:15
Height (xxx.x)	70 in
Weight (xxx.x)	180 lb
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682018

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 DEC 2020

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

US3682018

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 DEC 2020

US3682018

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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	SICKD1

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 FEB 2021
Time of assessment (00:00-23:59)	15:55 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 15:55
Height (xxx.x)	74 in
Weight (xxx.x)	90.6 kg
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682018

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 FEB 2021

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

US3682018

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 01 Apr 2021 20:38:28

Generated On: 11 Aug 2021 23:02:48

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

05 FEB 2021

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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	SICKD28

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	13:35 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 13:35
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:38:27

Generated On: 11 Aug 2021 23:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 JAN 2021

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

US3682018

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 01 Apr 2021 20:38:26

Generated On: 11 Aug 2021 23:02:48

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

08 JAN 2021

US3682018

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

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

Visit date (dd MMM yyyy)	27 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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US3682018

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Date of updated informed consent (<i>dd MMM yyyy</i>)	8 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	27 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3682018

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

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

US3682018

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JAN 2021
Time of assessment (00:00-23:59)	13:54 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 13:54
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3682018

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JAN 2021
Time of assessment (00:00-23:59)	14:39 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 14:39
Temperature (xxx.x)	98.7 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3682018

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

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JAN 2021

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

US3682018

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

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 27 JAN 2021

What was the treatment time? (00:00-23:59) 14:07 (24 HR)

Treatment Date and Time (derived) 27 JAN 2021 14:07

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

US3682018

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00-23:59)

13:51 (24 HR)

Collection date and time (derived)

27 JAN 2021 13:51

US3682018

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00 - 23:59)	13:53
Collection Date and Time (derived)	27 JAN 2021 13:53

US3682018

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

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:09:15

Generated On: 11 Aug 2021 23:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682018

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:09:15

Generated On: 11 Aug 2021 23:02:48

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

US3682018

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:28:30

Generated On: 11 Aug 2021 23:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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	OLD29

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 18:28:30

Generated On: 11 Aug 2021 23:02:48

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)	23 FEB 2021
Time of assessment (00:00-23:59)	13:37 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 13:37
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 18:28:30

Generated On: 11 Aug 2021 23:02:48

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)	23 FEB 2021
Time of assessment (00:00-23:59)	14:22 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 14:22
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3682018

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:28:30

Generated On: 11 Aug 2021 23:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3682018

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 25 Mar 2021 18:28:30

Generated On: 11 Aug 2021 23:02:48

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 13:52 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 13:52

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

US3682018

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:28:30

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:28:31

Generated On: 11 Aug 2021 23:02:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682018

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:28:31

Generated On: 11 Aug 2021 23:02:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682018

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:28:31

Generated On: 11 Aug 2021 23:02:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 18:28:31

Generated On: 11 Aug 2021 23:02:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:22 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 13:22
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682018

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:28:31

Generated On: 11 Aug 2021 23:02:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3682018

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 18:28:31

Generated On: 11 Aug 2021 23:02:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 MAR 2021

Collection time (00:00-23:59)

13:38 (24 HR)

Collection date and time (derived)

24 MAR 2021 13:38

US3682018

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 21:10:33

Generated On: 11 Aug 2021 23:02:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 SEP 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)	15 SEP 2020
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 (1)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

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	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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

AEID

Adverse event

VOMITING

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

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

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

AEID

Adverse event

SORE THROAT

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

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	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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

AEID	USA-US081-2020-MRNA-1273-P30 1000004
Adverse event	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)	9 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)	19 DEC 2020
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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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

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 Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PT DENIED MEDICAL INTERVENTION, AS WELL AS HOME TREATMENTS AND MEDICATIONS.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	
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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

AEID

Adverse event

STREP THROAT

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)

2 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

7 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

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 (5)

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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	

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Folder: Adverse Events

Form: Adverse Events (5)

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PARTICIPANT REPORTS ONSET
OF SORE THROAT ON EVENING
OF 2/2/2021, FOLLOWED BY
FATIGUE AND FEVER WITH
TMAX 100.5F ON 2/3/2021. SEEN
BY URGENT CARE ON 2/3/2021,
RAPID STREP TEST POSITIVE,
TREATED WITH
AZITHROMYCIN. ILLNESS VISIT
COMPLETED ON 2/5/2021.

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 (6)

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

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Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 21:10:01

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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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (6)

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PARTICIPATNT NOTES
INCREASED PHYSICAL
ACTIVITY RECENTLY AND
ONSET OF RIGHT
SHOULDER/ARM PAIN FOR
WHICH HE WAS PRESCRIBED A
MEDROL DOSE PACK WHICH
DID NOT HAVE A SIGNIFICANT
IMPACT ON SYMPTOMS. AT
THIS TIME, SYMPTOMS ARE
IMPROVING WITH INCREASED
STRETCHING ACTIVITIES.

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 (7)

Data signed: (b) (4) 22 Apr 2021 21:10:01

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AEID

Adverse event

ORAL HSV OUTBREAK

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)

18 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

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Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒
Related ☐
Not Applicable ☐

Relationship to Study Procedure Not Related ☒
Related ☐
Not Applicable ☐

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

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

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

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

Narrative PATIENT REPORTS HAVING LEFT LIP "COLD" SORE AND TAKING VALTREX OVER TWO DAYS, AS PRESCRIBED WHEN HE VISITED URGENT CARE

Serious Adverse Event Derived (CSA Programming Field Only) 0

Medically Attended AE Derived (CSA Programming Field Only) 1

Admitted to ICU Derived (CSA Programming Field Only)

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 21:10:01

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

AEID

Adverse event

LEFT HAND WOUND
SECONDARY TO DOG BITE

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)

18 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 22 Apr 2021 21:10:01

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

Form: Adverse Events (9)

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Admitted to ICU Derived (CSA Programming Field Only)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 01 Apr 2021 20:38:26

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 21:10:01

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Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 21:10:01

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 21:10:01

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Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication STREP THROAT

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

ONCE

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

	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)		3 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 3 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication STREP THROAT

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 (3)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

	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)	4 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 7 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

Name of Medication MEDROL DOSE PACK
(SOLUMEDROL, TAPERING DOSE)

Prophylaxis Yes ☐
No ☒

Indication RIGHT ARM/SHOULDER PAIN

Dose per administration UNK/UNKOWN

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

If dose unit is Other, specify TAPERING DOSE IN
MILLIGRAMS.

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 21:10:01

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	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)	18 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
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 (5)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

Name of Medication VALTREX

Prophylaxis Yes ☐
No ☒

Indication ORAL HSV OUTBREAK

Dose per administration UNKNOWN

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) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

	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)	18 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication LEFT HAND WOUND
SECONDARY TO DOG BITE

Dose per administration 100

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

	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)		19 APR 2021
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"/>

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication LEFT HAND WOUND
SECONDARY TO DOG BITE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 21:10:01

Generated On: 11 Aug 2021 23:02:48

	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)		19 APR 2021
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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3682018

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 20:38:26

Generated On: 11 Aug 2021 23:02:48

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3682018

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:02:48

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

US3682018

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 23:02:48

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 ☐

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

SAEID	USA-US081-2020-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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

SAEID	USA-US081-2020-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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	15/DEC/2020 09:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

SAEID	USA-US081-2020-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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	28/DEC/2020 19:15
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

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 01 Apr 2021 20:38:29

Generated On: 11 Aug 2021 23:02:48

SAEID	USA-US081-2020-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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	
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

US3682018 (Prod: UCLA Vine Street Clinic - (CRS))

US3682018

Form: Participant Creation

Generated On: 11 Aug 2021 23:02:48

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'US3682018'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:59:25

US3682018

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Yes (Y)'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:02:32
	(b) (4)	

US3682018

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:59:26

US3682018

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Clinic (Clinic)'	Jesse Clark (b) (4)	26 Aug 2020 20:02:32

US3682018

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'SCRN'	System	26 Aug 2020 20:02:32

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered (b) (6) 1979'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:59:26

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '40'	Jesse Clark (b) (4)	26 Aug 2020 20:03:01

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'YEARS'	System	26 Aug 2020 20:03:01

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered '40'	System	26 Aug 2020 20:03:23

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Male (M)'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:03:01
	(b) (4)	

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Jesse Clark (b) (4)	26 Aug 2020 20:03:01

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '0'	Jesse Clark (b) (4)	26 Aug 2020 20:03:01

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '0'	Jesse Clark (b) (4)	26 Aug 2020 20:03:01

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '0'	Jesse Clark (b) (4)	26 Aug 2020 20:03:01

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '0'	Jesse Clark (b) (4)	26 Aug 2020 20:03:01

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '0'	Jesse Clark (b) (4)	26 Aug 2020 20:03:01

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:57:21
User closed query 'Per CDM: response to Race is presently recorded as 'Other: Declines to Specify'. Please consider checking Not Reported and make all appropriate updates.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:48:29
Query 'Per CDM: response to Race is presently recorded as 'Other: Declines to Specify'. Please consider checking Not Reported and make all appropriate updates.' answered with 'Participant specified race as "Other" but declined to provide any further information.' (Site from DM).	Jesse Clark (b) (4) (b) (4)	05 Oct 2020 18:57:09
User opened query 'Per CDM: response to Race is presently recorded as 'Other: Declines to Specify'. Please consider checking Not Reported and make all appropriate updates.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 22:54:47
User entered '1'	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 20:03:01

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User closed query 'Per CDM: response to Race is presently recorded as 'Other: Declines to Specify'. Please consider checking Not Reported and make all appropriate updates.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 12:57:57
Query 'Per CDM: response to Race is presently recorded as 'Other: Declines to Specify'. Please consider checking Not Reported and make all appropriate updates.' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:57:30
User closed query 'Race has been reported as Other, however If race is Other, specify is missing. Please provide.' (Site from System).	System	15 Oct 2020 20:57:21
User opened query 'Race has been reported as Other, however If race is Other, specify is missing. Please provide.' (Site from System).	System	15 Oct 2020 20:57:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 20:57:07
User opened query 'Per CDM: response to Race is presently recorded as 'Other: Declines to Specify'. Please consider checking Not Reported and make all appropriate updates.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 12:19:00
User closed query 'Race has been reported as Other, however If race is Other, specify is missing. Please provide.' (Site from System).	System	26 Aug 2020 20:03:08
User entered 'Declines to specify' reason for change: Data Entry Error	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 20:03:08
User opened query 'Race has been reported as Other, however If race is Other, specify is missing. Please provide.' (Site from System).	System	26 Aug 2020 20:03:01
User entered empty.	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 20:03:01

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '0'	Jesse Clark (b) (4)	26 Aug 2020 20:03:01

US3682018

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:48

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User closed query 'Race is checked as Not reported, however, other Race options have also been checked. Please correct.' (Site from System).	(b) (4)	15 Oct 2020 20:57:21
User opened query 'Race is checked as Not reported, however, other Race options have also been checked. Please correct.' (Site from System).	System	15 Oct 2020 20:57:07
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 20:57:07
User entered '0'	Jesse Clark (b) (4)	26 Aug 2020 20:03:01
	(b) (4)	

US3682018

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:48

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '26 Aug 2020'	Jesse Clark (b) (4)	26 Aug 2020 20:03:23

US3682018

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'Aug 2020'	System	26 Aug 2020 20:03:23

US3682018

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered '2020'	System	26 Aug 2020 20:03:23

US3682018

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Amendment 3 (3)'	Jesse Clark (b) (4)	26 Aug 2020 20:03:23

US3682018

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Yes (Y)'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:03:23
	(b) (4)	

US3682018

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:48

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	26 Aug 2020 20:03:23

US3682018

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:03:23
	(b) (4)	

US3682018

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'No (N)'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:03:23
	(b) (4)	

US3682018

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:59:26

US3682018

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'I'	System	26 Aug 2020 20:03:28

US3682018

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Yes (Y)'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:03:28
	(b) (4)	

US3682018

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 23:02:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User closed query 'Per CDM: Age of the subject is >25 years. However, no medical history is collected. Please confirm or update as needed, else please clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 04:17:40
Query 'Per CDM: Age of the subject is >25 years. However, no medical history is collected. Please confirm or update as needed, else please clarify. ' answered with 'Participant denies history of medical problems or surgery' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 19:05:30
User opened query 'Per CDM: Age of the subject is >25 years. However, no medical history is collected. Please confirm or update as needed, else please clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 10:58:15
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 20:03:34

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Yes (Y)'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:14:16
	(b) (4)	

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '26 Aug 2020'	Jesse Clark (b) (4)	26 Aug 2020 20:14:16

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '13:05'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:14:16
	(b) (4)	

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered '26 Aug 2020 13:05'	System	26 Aug 2020 20:14:16

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '74' in	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:14:16
	(b) (4)	
DataPoint set to visible.	System	26 Aug 2020 20:03:28

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '91' kg	(b) (4) Jesse Clark (b) (4)	26 Aug 2020 20:14:16
DataPoint set to visible.	(b) (4) System	26 Aug 2020 20:03:28

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
Amendment Manager: User entered '25.75790'	System	17 Sep 2020 00:04:24
User entered '25.8'	System	26 Aug 2020 20:14:16
DataPoint set to visible.	System	26 Aug 2020 20:03:28

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'kg/m2'	System	26 Aug 2020 20:14:16
DataPoint set to visible.	System	26 Aug 2020 20:03:28

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User closed query 'Re-Query :Per CDM: Response noted, kindly consider updating the unit as Blank as Temperature is ND. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 05:25:46
Query 'Re-Query :Per CDM: Response noted, kindly consider updating the unit as Blank as Temperature is ND. ' answered with 'will do' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 16:48:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:48:08
User opened query 'Re-Query :Per CDM: Response noted, kindly consider updating the unit as Blank as Temperature is ND. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 06:23:39
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 06:23:39
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'Screening and visit 1 done same day' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Sep 2020 18:28:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Susan Reed (b) (4) (b) (4)	09 Sep 2020 18:28:19

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM). User entered '97.5' F	(b) (4), (b) (6) Jesse Clark (b) (4) (b) (4)	09 Sep 2020 17:51:17 26 Aug 2020 20:14:16

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered empty; reason for change Data Entry Error	(b) (4)	
	Susan Reed (b) (4)	09 Sep 2020 18:28:19
User entered 'Oral (Oral)'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:14:16
	(b) (4)	

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	26 Aug 2020 20:14:16

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 18:28:19
User entered '53'	Susan Reed (b) (4)	26 Aug 2020 20:14:16
	(b) (4)	

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'bpm'	System	26 Aug 2020 20:14:16

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 18:28:19
User entered '16'	Susan Reed (b) (4)	26 Aug 2020 20:14:16
	(b) (4)	

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'breaths/min'	System	26 Aug 2020 20:14:16

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 18:28:19
User entered '110'	Susan Reed (b) (4)	26 Aug 2020 20:14:16
	(b) (4)	

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'mmHg'	System	26 Aug 2020 20:14:16

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 18:28:19
User entered '70'	Susan Reed (b) (4)	26 Aug 2020 20:14:16
	(b) (4)	

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'mmHg'	System	26 Aug 2020 20:14:16

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51

US3682018

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51

US3682018

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Yes (Y)'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:09:39
	(b) (4)	

US3682018

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '26 Aug 2020'	Jesse Clark (b) (4)	26 Aug 2020 20:09:39

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'No (N)'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'No (N)'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

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)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'No (N)'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

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)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'No (N)'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'No (N)'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:10:23
	(b) (4)	

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

[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)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'No (N)'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

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)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'No (N)'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

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)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'No (N)'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'No (N)'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:10:23
	(b) (4)	

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

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)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'No (N)'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

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)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'No (N)'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'No (N)'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:10:23
	(b) (4)	

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:10:23
	(b) (4)	

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:10:23
	(b) (4)	

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '0'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

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)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '0'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

[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)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '0'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

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)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '0'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'I'	Jesse Clark (b) (4)	26 Aug 2020 20:10:23

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '0'	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:10:23
	(b) (4)	

US3682018

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	26 Aug 2020 20:10:23
	(b) (4)	

US3682018

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:48:03

US3682018

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '26 Aug 2020'	(b) (4) Simone Riley (b) (4)	26 Aug 2020 22:48:03

US3682018

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Clinic (Clinic)'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:48:03

US3682018

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'VISIT1'	System	26 Aug 2020 22:48:03

US3682018

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 20:24:31

US3682018

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:48

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '108508'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 20:24:31

US3682018

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 20:24:31

US3682018

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:48

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)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User closed query ' PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:47:07
Query ' PER CDM: Please complete this section of the form.' answered with 'Completed' (Site from DM).	Susan Reed (b) (4) (b) (4)	31 Aug 2020 20:44:53
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	31 Aug 2020 20:44:43
User opened query ' PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 20:00:27

US3682018

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:48

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)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'No (N)'	Susan Reed (b) (4)	31 Aug 2020 20:44:43

US3682018

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	31 Aug 2020 20:44:43

US3682018

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:48

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	31 Aug 2020 20:44:43

US3682018

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	31 Aug 2020 20:44:43

US3682018

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:48

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 04:10:40
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'data added' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	08 Dec 2020 00:42:06
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	08 Dec 2020 00:41:59
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 23:31:21
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:08:06
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:08:05

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User closed query 'Per CDM: Re-query: Please update as ND in weight data point as well. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:39:51
Query 'Per CDM: Re-query: Please update as ND in weight data point as well. Thank you.' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 16:48:53
User opened query 'Per CDM: Re-query: Please update as ND in weight data point as well. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:26:47
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:26:47
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening and visit 1 done same day' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Sep 2020 18:28:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Susan Reed (b) (4) (b) (4)	09 Sep 2020 18:28:34
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 17:51:28
User entered empty.	Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:48:42
User entered empty.	Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User closed query 'Per CDM: Re-query: Please update as ND in weight data point as well. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:39:51
Query 'Per CDM: Re-query: Please update as ND in weight data point as well. Thank you.' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 16:48:53
User opened query 'Per CDM: Re-query: Please update as ND in weight data point as well. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:26:47
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:26:47
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening and visit 1 done same day' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Sep 2020 18:28:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Susan Reed (b) (4) (b) (4)	09 Sep 2020 18:28:34
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 17:51:28
User entered empty.	Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:48:42
User entered empty.	Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User accepted default value 'Pre-Dose (PREDOSE)'	Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '26 Aug 2020'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '13:05'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered '26 Aug 2020 13:05'	System	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '97.5' F	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Oral (Oral)'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered empty.	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '53'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'bpm'	System	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '16'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'breaths/min'	System	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '110'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'mmHg'	System	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '70'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'mmHg'	System	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User closed query 'Per CDM: Re-query: Please update as ND in weight data point as well. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:39:51
Query 'Per CDM: Re-query: Please update as ND in weight data point as well. Thank you.' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 16:48:53
User opened query 'Per CDM: Re-query: Please update as ND in weight data point as well. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:26:47
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:26:47
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening and visit 1 done same day' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Sep 2020 18:28:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Susan Reed (b) (4) (b) (4)	09 Sep 2020 18:28:34
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 17:51:28
User entered empty.	Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:48:42
User entered empty.	Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User accepted default value 'Post-Dose (POSTDOSE)'	Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	26 Aug 2020 22:49:50
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 22:49:50
User entered '26 Aug 2020' reason for change: Data Entry Error	Simone Riley (b) (4)	26 Aug 2020 22:49:50
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	26 Aug 2020 22:49:32
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 22:49:32
User entered '26 Aug 2029'	Simone Riley (b) (4)	26 Aug 2020 22:49:32
	(b) (4)	

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '14:31'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered '26 Aug 2020 14:31'	System	26 Aug 2020 22:49:50
User entered '26 Aug 2029 14:31'	System	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '98.2' F	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Oral (Oral)'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered empty.	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '52'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'bpm'	System	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '14'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'breaths/min'	System	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '109'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'mmHg'	System	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '71'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'mmHg'	System	26 Aug 2020 22:49:32

US3682018

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	28 Aug 2020 16:05:39

US3682018

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '26 Aug 2020'	(b) (4) Simone Riley (b) (4) (b) (4)	28 Aug 2020 16:05:39

US3682018

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 21:01:05

US3682018

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered empty.	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 21:01:05

US3682018

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered empty.	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 21:01:05

US3682018

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 21:01:05

US3682018

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '26 Aug 2020'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 21:01:05

US3682018

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '13:56'	(b) (4) Simone Riley (b) (4) (b) (4)	26 Aug 2020 21:01:05

US3682018

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered '26 Aug 2020 13:56'	System	26 Aug 2020 21:01:05

US3682018

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Left Arm (LEFT ARM)'	Simone Riley (b) (4)	26 Aug 2020 21:01:05

US3682018

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'ONCE'	System	26 Aug 2020 21:01:05

US3682018

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 21:01:05

US3682018

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:10:24

US3682018

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:10:24

US3682018

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '13:48'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:10:24

US3682018

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered '26 Aug 2020 13:48'	System	26 Aug 2020 23:10:24

US3682018

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:10:51

US3682018

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	26 Aug 2020 23:10:51

US3682018

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:10:51

US3682018

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '13:51'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:10:51

US3682018

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered '26 Aug 2020 13:51'	System	26 Aug 2020 23:10:51

US3682018

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	26 Aug 2020 23:10:51

US3682018

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:10:51

US3682018

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:10:51

US3682018

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered empty.	System	26 Aug 2020 23:10:51

US3682018

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	02 Sep 2020 19:57:45

US3682018

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'I'	System	02 Sep 2020 19:57:45

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:26:36', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9f167448-42c4-445d-8aa8-e3762013de16' User entered 'Yes (Y)'	System	26 Aug 2020 21:27:05
	System	26 Aug 2020 21:27:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:26:45', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9f167448-42c4-445d-8aa8-e3762013de16' User entered '97.5'	System	26 Aug 2020 21:27:05
	System	26 Aug 2020 21:27:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:26:51', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9f167448-42c4-445d-8aa8-e3762013de16'	System	26 Aug 2020 21:27:05
User entered 'No (N)'	System	26 Aug 2020 21:27:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:27:03', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9f167448-42c4-445d-8aa8-e3762013de16' User entered '26 Aug 2020 14:27'	System	26 Aug 2020 21:27:05
	System	26 Aug 2020 21:27:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Aug 2020 14:16'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Aug 2020 16:46'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:18:12', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a06ef2f5-8029-4dcf-a1c3-c390b501a27f' User entered 'Yes (Y)'	System	27 Aug 2020 17:18:43
	System	27 Aug 2020 17:18:43

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:18:22', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a06ef2f5-8029-4dcf-a1c3-c390b501a27f' User entered '97.0'	System	27 Aug 2020 17:18:43
	System	27 Aug 2020 17:18:43

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:18:27', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a06ef2f5-8029-4dcf-a1c3-c390b501a27f'	System	27 Aug 2020 17:18:43
User entered 'No (N)'	System	27 Aug 2020 17:18:43

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:18:41', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a06ef2f5-8029-4dcf-a1c3-c390b501a27f' User entered '27 Aug 2020 10:18'	System	27 Aug 2020 17:18:43
	System	27 Aug 2020 17:18:43

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Aug 2020 17:41'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 2'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:31:12', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'fd93aad2-fd65-4dde-9d7e-07209a3377b2' User entered 'Yes (Y)'	System	28 Aug 2020 18:31:37
	System	28 Aug 2020 18:31:37

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:31:19', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'fd93aad2-fd65-4dde-9d7e-07209a3377b2' User entered '97.5'	System	28 Aug 2020 18:31:37
	System	28 Aug 2020 18:31:37

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:31:23', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'fd93aad2-fd65-4dde-9d7e-07209a3377b2'	System	28 Aug 2020 18:31:37
User entered 'No (N)'	System	28 Aug 2020 18:31:37

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:31:34', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'fd93aad2-fd65-4dde-9d7e-07209a3377b2' User entered '28 Aug 2020 11:31'	System	28 Aug 2020 18:31:37
	System	28 Aug 2020 18:31:37

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 3'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T12:00:36', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '46615a96-49ed-4f26-ab6e-2a1d63894237'	System	29 Aug 2020 13:49:46
User entered 'Yes (Y)'	System	29 Aug 2020 13:49:46

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:49:34', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '46615a96-49ed-4f26-ab6e-2a1d63894237' User entered '98.1'	System	29 Aug 2020 13:49:46
	System	29 Aug 2020 13:49:46

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:49:38', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '46615a96-49ed-4f26-ab6e-2a1d63894237'	System	29 Aug 2020 13:49:46
User entered 'No (N)'	System	29 Aug 2020 13:49:46

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:49:43', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '46615a96-49ed-4f26-ab6e-2a1d63894237' User entered '29 Aug 2020 06:49'	System	29 Aug 2020 13:49:46
	System	29 Aug 2020 13:49:46

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 4'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:10:48', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '4c233e94-33c0-4e1f-ab4a-2e4507fca73b' User entered 'Yes (Y)'	System	30 Aug 2020 17:11:14
	System	30 Aug 2020 17:11:14

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:10:58', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '4c233e94-33c0-4e1f-ab4a-2e4507fca73b' User entered '97.0'	System	30 Aug 2020 17:11:14
	System	30 Aug 2020 17:11:14

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:11:04', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '4c233e94-33c0-4e1f-ab4a-2e4507fca73b' User entered 'No (N)'	System	30 Aug 2020 17:11:14
	System	30 Aug 2020 17:11:14

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:11:12', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '4c233e94-33c0-4e1f-ab4a-2e4507fca73b' User entered '30 Aug 2020 10:11'	System	30 Aug 2020 17:11:14
	System	30 Aug 2020 17:11:14

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 5'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:35:04', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '5f003b7a-7c2d-4728-8a7d-86ac346df6db' User entered 'Yes (Y)'	System	31 Aug 2020 18:35:40
	System	31 Aug 2020 18:35:40

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:35:13', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '5f003b7a-7c2d-4728-8a7d-86ac346df6db' User entered '96.5'	System	31 Aug 2020 18:35:40
	System	31 Aug 2020 18:35:40

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:35:17', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '5f003b7a-7c2d-4728-8a7d-86ac346df6db' User entered 'No (N)'	System	31 Aug 2020 18:35:40
	System	31 Aug 2020 18:35:40

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:35:34', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '5f003b7a-7c2d-4728-8a7d-86ac346df6db' User entered '31 Aug 2020 11:35'	System	31 Aug 2020 18:35:40
	System	31 Aug 2020 18:35:40

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 6'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:01:15', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'afbd04cf-ee4d-4cef-8ecf-0c040d63b043'	System	01 Sep 2020 13:01:36
User entered 'Yes (Y)'	System	01 Sep 2020 13:01:36

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:01:21', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'afbd04cf-ee4d-4cef-8ecf-0c040d63b043' User entered '97.3'	System	01 Sep 2020 13:01:36
	System	01 Sep 2020 13:01:36

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:01:27', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'afbd04cf-ee4d-4cef-8ecf-0c040d63b043'	System	01 Sep 2020 13:01:36
User entered 'No (N)'	System	01 Sep 2020 13:01:36

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:01:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'afbd04cf-ee4d-4cef-8ecf-0c040d63b043'	System	01 Sep 2020 13:01:36
User entered '01 Sep 2020 06:01'	System	01 Sep 2020 13:01:36

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 7'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:42:07', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '278b1fa2-5f08-41eb-9ffb-df0116a10e48'	System	02 Sep 2020 06:42:32
User entered 'Yes (Y)'	System	02 Sep 2020 06:42:32

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:42:16', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '278b1fa2-5f08-41eb-9ffb-df0116a10e48' User entered '96.5'	System	02 Sep 2020 06:42:32
	System	02 Sep 2020 06:42:32

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:42:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '278b1fa2-5f08-41eb-9ffb-df0116a10e48'	System	02 Sep 2020 06:42:32
User entered 'No (N)'	System	02 Sep 2020 06:42:32

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:42:30', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '278b1fa2-5f08-41eb-9ffb-df0116a10e48'	System	02 Sep 2020 06:42:32
User entered '01 Sep 2020 23:42'	System	02 Sep 2020 06:42:32

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:27:16', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'c81e70bf-de8a-4f12-9522-8032a79c8aa3'	System	26 Aug 2020 21:27:53
User entered 'None (1)'	System	26 Aug 2020 21:27:53

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:27:27', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'c81e70bf-de8a-4f12-9522-8032a79c8aa3'	System	26 Aug 2020 21:27:53
User entered 'No (N)'	System	26 Aug 2020 21:27:53

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:27:36', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'c81e70bf-de8a-4f12-9522-8032a79c8aa3'	System	26 Aug 2020 21:27:53
User entered 'No (N)'	System	26 Aug 2020 21:27:53

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:27:46', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'c81e70bf-de8a-4f12-9522-8032a79c8aa3'	System	26 Aug 2020 21:27:53
User entered 'None (1)'	System	26 Aug 2020 21:27:53

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:27:50', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'c81e70bf-de8a-4f12-9522-8032a79c8aa3' User entered '26 Aug 2020 14:27'	System	26 Aug 2020 21:27:53
	System	26 Aug 2020 21:27:53

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Aug 2020 14:16'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Aug 2020 16:46'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:18:59', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'feda48d6-2eaa-4548-8186-dd57cf84a848'	System	27 Aug 2020 17:19:47
User entered 'None (1)'	System	27 Aug 2020 17:19:47

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:19:23', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'feda48d6-2eaa-4548-8186-dd57cf84a848'	System	27 Aug 2020 17:19:47
User entered 'No (N)'	System	27 Aug 2020 17:19:47

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:19:27', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'feda48d6-2eaa-4548-8186-dd57cf84a848'	System	27 Aug 2020 17:19:47
User entered 'No (N)'	System	27 Aug 2020 17:19:47

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:19:32', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'feda48d6-2eaa-4548-8186-dd57cf84a848'	System	27 Aug 2020 17:19:47
User entered 'None (1)'	System	27 Aug 2020 17:19:47

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:19:43', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'feda48d6-2eaa-4548-8186-dd57cf84a848' User entered '27 Aug 2020 10:19'	System	27 Aug 2020 17:19:47
	System	27 Aug 2020 17:19:47

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Aug 2020 17:41'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 2'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:31:43', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '979d35a8-ec9f-47c4-94e5-41687dd63d45'	System	28 Aug 2020 18:32:07
User entered 'None (1)'	System	28 Aug 2020 18:32:07

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:31:51', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '979d35a8-ec9f-47c4-94e5-41687dd63d45'	System	28 Aug 2020 18:32:07
User entered 'No (N)'	System	28 Aug 2020 18:32:07

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:31:56', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '979d35a8-ec9f-47c4-94e5-41687dd63d45' User entered 'No (N)'	System	28 Aug 2020 18:32:07
	System	28 Aug 2020 18:32:07

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:32:01', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '979d35a8-ec9f-47c4-94e5-41687dd63d45'	System	28 Aug 2020 18:32:07
User entered 'None (1)'	System	28 Aug 2020 18:32:07

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:32:05', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '979d35a8-ec9f-47c4-94e5-41687dd63d45' User entered '28 Aug 2020 11:32'	System	28 Aug 2020 18:32:07
	System	28 Aug 2020 18:32:07

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 3'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:49:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '26d0f4c8-7655-4490-824c-084f9f0aac8a'	System	29 Aug 2020 13:50:01
User entered 'None (1)'	System	29 Aug 2020 13:50:01

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:49:50', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '26d0f4c8-7655-4490-824c-084f9f0aac8a' User entered 'No (N)'	System	29 Aug 2020 13:50:01
	System	29 Aug 2020 13:50:01

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:49:52', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '26d0f4c8-7655-4490-824c-084f9f0aac8a'	System	29 Aug 2020 13:50:01
User entered 'No (N)'	System	29 Aug 2020 13:50:01

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:49:54', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '26d0f4c8-7655-4490-824c-084f9f0aac8a'	System	29 Aug 2020 13:50:01
User entered 'None (1)'	System	29 Aug 2020 13:50:01

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:49:57', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '26d0f4c8-7655-4490-824c-084f9f0aac8a' User entered '29 Aug 2020 06:49'	System	29 Aug 2020 13:50:01
	System	29 Aug 2020 13:50:01

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 4'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:11:18', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '093cb622-4cbd-444d-9637-e7ed4c107d08'	System	30 Aug 2020 17:11:34
User entered 'None (1)'	System	30 Aug 2020 17:11:34

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:11:21', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '093cb622-4cbd-444d-9637-e7ed4c107d08'	System	30 Aug 2020 17:11:34
User entered 'No (N)'	System	30 Aug 2020 17:11:34

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:11:26', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '093cb622-4cbd-444d-9637-e7ed4c107d08'	System	30 Aug 2020 17:11:34
User entered 'No (N)'	System	30 Aug 2020 17:11:34

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:11:28', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '093cb622-4cbd-444d-9637-e7ed4c107d08'	System	30 Aug 2020 17:11:34
User entered 'None (1)'	System	30 Aug 2020 17:11:34

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:11:32', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '093cb622-4cbd-444d-9637-e7ed4c107d08' User entered '30 Aug 2020 10:11'	System	30 Aug 2020 17:11:34
	System	30 Aug 2020 17:11:34

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 5'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:35:40', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '41020a4d-a043-41fb-998a-44bf212b25db' User entered 'None (1)'	System	31 Aug 2020 18:36:02
	System	31 Aug 2020 18:36:02

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:35:44', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '41020a4d-a043-41fb-998a-44bf212b25db' User entered 'No (N)'	System	31 Aug 2020 18:36:02
	System	31 Aug 2020 18:36:02

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:35:46', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '41020a4d-a043-41fb-998a-44bf212b25db' User entered 'No (N)'	System	31 Aug 2020 18:36:02
	System	31 Aug 2020 18:36:02

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:35:49', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '41020a4d-a043-41fb-998a-44bf212b25db' User entered 'None (1)'	System	31 Aug 2020 18:36:02
	System	31 Aug 2020 18:36:02

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:36:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '41020a4d-a043-41fb-998a-44bf212b25db' User entered '31 Aug 2020 11:36'	System	31 Aug 2020 18:36:02
	System	31 Aug 2020 18:36:02

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 6'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:01:38', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '556104b3-05c0-4be0-9184-4a2cf553ab53' User entered 'None (1)'	System	01 Sep 2020 13:01:56
	System	01 Sep 2020 13:01:56

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:01:44', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '556104b3-05c0-4be0-9184-4a2cf553ab53' User entered 'No (N)'	System	01 Sep 2020 13:01:56
	System	01 Sep 2020 13:01:56

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:01:49', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '556104b3-05c0-4be0-9184-4a2cf553ab53' User entered 'No (N)'	System	01 Sep 2020 13:01:56
	System	01 Sep 2020 13:01:56

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:01:51', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '556104b3-05c0-4be0-9184-4a2cf553ab53'	System	01 Sep 2020 13:01:56
User entered 'None (1)'	System	01 Sep 2020 13:01:56

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:01:54', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '556104b3-05c0-4be0-9184-4a2cf553ab53' User entered '01 Sep 2020 06:01'	System	01 Sep 2020 13:01:56
	System	01 Sep 2020 13:01:56

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 7'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:42:35', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '4065f151-8d1e-4c5b-9928-73c5326d4317'	System	02 Sep 2020 06:42:48
User entered 'None (1)'	System	02 Sep 2020 06:42:48

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:42:38', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '4065f151-8d1e-4c5b-9928-73c5326d4317'	System	02 Sep 2020 06:42:48
User entered 'No (N)'	System	02 Sep 2020 06:42:48

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:42:41', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '4065f151-8d1e-4c5b-9928-73c5326d4317'	System	02 Sep 2020 06:42:48
User entered 'No (N)'	System	02 Sep 2020 06:42:48

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:42:43', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '4065f151-8d1e-4c5b-9928-73c5326d4317' User entered 'None (1)'	System	02 Sep 2020 06:42:48
	System	02 Sep 2020 06:42:48

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:42:46', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '4065f151-8d1e-4c5b-9928-73c5326d4317' User entered '01 Sep 2020 23:42'	System	02 Sep 2020 06:42:48
	System	02 Sep 2020 06:42:48

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:27:56', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '880306e7-f974-4ee3-89bb-b72ec273566e' User entered 'None (0)'	System	26 Aug 2020 21:28:23
	System	26 Aug 2020 21:28:23

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:27:59', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '880306e7-f974-4ee3-89bb-b72ec273566e' User entered 'None (0)'	System	26 Aug 2020 21:28:23
	System	26 Aug 2020 21:28:23

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:28:02', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '880306e7-f974-4ee3-89bb-b72ec273566e' User entered 'None (0)'	System	26 Aug 2020 21:28:23
	System	26 Aug 2020 21:28:23

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:28:04', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '880306e7-f974-4ee3-89bb-b72ec273566e' User entered 'None (0)'	System	26 Aug 2020 21:28:23
	System	26 Aug 2020 21:28:23

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:28:07', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '880306e7-f974-4ee3-89bb-b72ec273566e' User entered 'None (0)'	System	26 Aug 2020 21:28:23
	System	26 Aug 2020 21:28:23

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:28:09', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '880306e7-f974-4ee3-89bb-b72ec273566e' User entered 'None (0)'	System	26 Aug 2020 21:28:23
	System	26 Aug 2020 21:28:23

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:28:16', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '880306e7-f974-4ee3-89bb-b72ec273566e' User entered 'No (N)'	System	26 Aug 2020 21:28:23
	System	26 Aug 2020 21:28:23

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-26T14:28:19', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '880306e7-f974-4ee3-89bb-b72ec273566e' User entered '26 Aug 2020 14:28'	System	26 Aug 2020 21:28:23
	System	26 Aug 2020 21:28:23

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Aug 2020 14:16'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Aug 2020 16:46'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:19:51', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'c3475ed3-86cf-4fb9-bf9c-621ca928e32e' User entered 'None (0)'	System	27 Aug 2020 17:20:12
	System	27 Aug 2020 17:20:12

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:19:54', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'c3475ed3-86cf-4fb9-bf9c-621ca928e32e' User entered 'None (0)'	System	27 Aug 2020 17:20:12
	System	27 Aug 2020 17:20:12

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:19:56', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'c3475ed3-86cf-4fb9-bf9c-621ca928e32e' User entered 'None (0)'	System	27 Aug 2020 17:20:12
	System	27 Aug 2020 17:20:12

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:19:58', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'c3475ed3-86cf-4fb9-bf9c-621ca928e32e' User entered 'None (0)'	System	27 Aug 2020 17:20:12
	System	27 Aug 2020 17:20:12

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:20:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'c3475ed3-86cf-4fb9-bf9c-621ca928e32e' User entered 'None (0)'	System	27 Aug 2020 17:20:12
	System	27 Aug 2020 17:20:12

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:20:01', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'c3475ed3-86cf-4fb9-bf9c-621ca928e32e' User entered 'None (0)'	System	27 Aug 2020 17:20:12
	System	27 Aug 2020 17:20:12

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:20:07', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'c3475ed3-86cf-4fb9-bf9c-621ca928e32e' User entered 'No (N)'	System	27 Aug 2020 17:20:12
	System	27 Aug 2020 17:20:12

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-27T10:20:11', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'c3475ed3-86cf-4fb9-bf9c-621ca928e32e' User entered '27 Aug 2020 10:20'	System	27 Aug 2020 17:20:12
	System	27 Aug 2020 17:20:12

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Aug 2020 17:41'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 2'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:32:09', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd5e2844d-d4b3-42ab-92f3-fd684aa98760' User entered 'None (0)'	System	28 Aug 2020 18:32:29
	System	28 Aug 2020 18:32:29

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:32:11', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd5e2844d-d4b3-42ab-92f3-fd684aa98760' User entered 'None (0)'	System	28 Aug 2020 18:32:29
	System	28 Aug 2020 18:32:29

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:32:13', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd5e2844d-d4b3-42ab-92f3-fd684aa98760' User entered 'None (0)'	System	28 Aug 2020 18:32:29
	System	28 Aug 2020 18:32:29

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:32:16', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd5e2844d-d4b3-42ab-92f3-fd684aa98760' User entered 'None (0)'	System	28 Aug 2020 18:32:29
	System	28 Aug 2020 18:32:29

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:32:19', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd5e2844d-d4b3-42ab-92f3-fd684aa98760' User entered 'None (0)'	System	28 Aug 2020 18:32:29
	System	28 Aug 2020 18:32:29

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:32:20', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd5e2844d-d4b3-42ab-92f3-fd684aa98760' User entered 'None (0)'	System	28 Aug 2020 18:32:29
	System	28 Aug 2020 18:32:29

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:32:23', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd5e2844d-d4b3-42ab-92f3-fd684aa98760' User entered 'No (N)'	System	28 Aug 2020 18:32:29
	System	28 Aug 2020 18:32:29

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-28T11:32:26', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd5e2844d-d4b3-42ab-92f3-fd684aa98760' User entered '28 Aug 2020 11:32'	System	28 Aug 2020 18:32:29
	System	28 Aug 2020 18:32:29

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 3'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:50:01', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '01f924eb-05d9-4bb6-8972-c62f7f548d42'	System	29 Aug 2020 13:50:22
User entered 'None (0)'	System	29 Aug 2020 13:50:22

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:50:04', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '01f924eb-05d9-4bb6-8972-c62f7f548d42'	System	29 Aug 2020 13:50:22
User entered 'None (0)'	System	29 Aug 2020 13:50:22

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:50:05', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '01f924eb-05d9-4bb6-8972-c62f7f548d42' User entered 'None (0)'	System	29 Aug 2020 13:50:22
	System	29 Aug 2020 13:50:22

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:50:07', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '01f924eb-05d9-4bb6-8972-c62f7f548d42'	System	29 Aug 2020 13:50:22
User entered 'None (0)'	System	29 Aug 2020 13:50:22

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:50:09', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '01f924eb-05d9-4bb6-8972-c62f7f548d42' User entered 'None (0)'	System	29 Aug 2020 13:50:22
	System	29 Aug 2020 13:50:22

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:50:10', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '01f924eb-05d9-4bb6-8972-c62f7f548d42' User entered 'None (0)'	System	29 Aug 2020 13:50:22
	System	29 Aug 2020 13:50:22

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:50:16', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '01f924eb-05d9-4bb6-8972-c62f7f548d42'	System	29 Aug 2020 13:50:22
User entered 'No (N)'	System	29 Aug 2020 13:50:22

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-29T06:50:19', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '01f924eb-05d9-4bb6-8972-c62f7f548d42' User entered '29 Aug 2020 06:50'	System	29 Aug 2020 13:50:22
	System	29 Aug 2020 13:50:22

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 4'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:11:53', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'efbdc92a-cc2e-41b8-ac62-1160fe25e892'	System	30 Aug 2020 17:12:26
User entered 'None (0)'	System	30 Aug 2020 17:12:26

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:12:07', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'efbdc92a-cc2e-41b8-ac62-1160fe25e892'	System	30 Aug 2020 17:12:26
User entered 'None (0)'	System	30 Aug 2020 17:12:26

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:12:11', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'efbdc92a-cc2e-41b8-ac62-1160fe25e892'	System	30 Aug 2020 17:12:26
User entered 'None (0)'	System	30 Aug 2020 17:12:26

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:12:13', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'efbdc92a-cc2e-41b8-ac62-1160fe25e892' User entered 'None (0)'	System	30 Aug 2020 17:12:26
	System	30 Aug 2020 17:12:26

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:12:16', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'efbdc92a-cc2e-41b8-ac62-1160fe25e892' User entered 'None (0)'	System	30 Aug 2020 17:12:26
	System	30 Aug 2020 17:12:26

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:12:18', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'efbdc92a-cc2e-41b8-ac62-1160fe25e892'	System	30 Aug 2020 17:12:26
User entered 'None (0)'	System	30 Aug 2020 17:12:26

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:12:22', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'efbdc92a-cc2e-41b8-ac62-1160fe25e892'	System	30 Aug 2020 17:12:26
User entered 'No (N)'	System	30 Aug 2020 17:12:26

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-30T10:12:24', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'efbdc92a-cc2e-41b8-ac62-1160fe25e892'	System	30 Aug 2020 17:12:26
User entered '30 Aug 2020 10:12'	System	30 Aug 2020 17:12:26

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 5'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:36:04', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1d2ce276-90f0-4f9f-bcdb-660ecffff477'	System	31 Aug 2020 18:36:32
User entered 'None (0)'	System	31 Aug 2020 18:36:32

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:36:09', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1d2ce276-90f0-4f9f-bcdb-660ecffff477'	System	31 Aug 2020 18:36:32
User entered 'None (0)'	System	31 Aug 2020 18:36:32

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:36:10', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1d2ce276-90f0-4f9f-bcdb-660ecffff477'	System	31 Aug 2020 18:36:32
User entered 'None (0)'	System	31 Aug 2020 18:36:32

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:36:12', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1d2ce276-90f0-4f9f-bcdb-660ecffff477'	System	31 Aug 2020 18:36:32
User entered 'None (0)'	System	31 Aug 2020 18:36:32

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:36:14', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1d2ce276-90f0-4f9f-bcdb-660ecffff477'	System	31 Aug 2020 18:36:32
User entered 'None (0)'	System	31 Aug 2020 18:36:32

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:36:19', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1d2ce276-90f0-4f9f-bcdb-660ecffff477'	System	31 Aug 2020 18:36:32
User entered 'None (0)'	System	31 Aug 2020 18:36:32

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:36:27', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1d2ce276-90f0-4f9f-bcdb-660ecffff477'	System	31 Aug 2020 18:36:32
User entered 'No (N)'	System	31 Aug 2020 18:36:32

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-08-31T11:36:30', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1d2ce276-90f0-4f9f-bcdb-660ecffff477'	System	31 Aug 2020 18:36:32
User entered '31 Aug 2020 11:36'	System	31 Aug 2020 18:36:32

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 6'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:01:58', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '3c6eae62-f527-4d38-ab6f-226a0f408878' User entered 'None (0)'	System	01 Sep 2020 13:02:19
	System	01 Sep 2020 13:02:19

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:02:01', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '3c6eae62-f527-4d38-ab6f-226a0f408878' User entered 'None (0)'	System	01 Sep 2020 13:02:19
	System	01 Sep 2020 13:02:19

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:02:02', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '3c6eae62-f527-4d38-ab6f-226a0f408878' User entered 'None (0)'	System	01 Sep 2020 13:02:19
	System	01 Sep 2020 13:02:19

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:02:04', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '3c6eae62-f527-4d38-ab6f-226a0f408878' User entered 'None (0)'	System	01 Sep 2020 13:02:19
	System	01 Sep 2020 13:02:19

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:02:06', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '3c6eae62-f527-4d38-ab6f-226a0f408878' User entered 'None (0)'	System	01 Sep 2020 13:02:19
	System	01 Sep 2020 13:02:19

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:02:08', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '3c6eae62-f527-4d38-ab6f-226a0f408878' User entered 'None (0)'	System	01 Sep 2020 13:02:19
	System	01 Sep 2020 13:02:19

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:02:14', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '3c6eae62-f527-4d38-ab6f-226a0f408878' User entered 'No (N)'	System	01 Sep 2020 13:02:19
	System	01 Sep 2020 13:02:19

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T06:02:16', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '3c6eae62-f527-4d38-ab6f-226a0f408878' User entered '01 Sep 2020 06:02'	System	01 Sep 2020 13:02:19
	System	01 Sep 2020 13:02:19

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 7'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:42:51', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '7d1f8da4-05bd-4da4-a2db-c8b7b594613b' User entered 'None (0)'	System	02 Sep 2020 06:43:18
	System	02 Sep 2020 06:43:18

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:42:53', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '7d1f8da4-05bd-4da4-a2db-c8b7b594613b' User entered 'None (0)'	System	02 Sep 2020 06:43:18
	System	02 Sep 2020 06:43:18

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:42:56', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '7d1f8da4-05bd-4da4-a2db-c8b7b594613b' User entered 'None (0)'	System	02 Sep 2020 06:43:18
	System	02 Sep 2020 06:43:18

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:42:59', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '7d1f8da4-05bd-4da4-a2db-c8b7b594613b' User entered 'None (0)'	System	02 Sep 2020 06:43:18
	System	02 Sep 2020 06:43:18

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:43:01', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '7d1f8da4-05bd-4da4-a2db-c8b7b594613b' User entered 'None (0)'	System	02 Sep 2020 06:43:18
	System	02 Sep 2020 06:43:18

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:43:03', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '7d1f8da4-05bd-4da4-a2db-c8b7b594613b' User entered 'None (0)'	System	02 Sep 2020 06:43:18
	System	02 Sep 2020 06:43:18

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:43:09', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '7d1f8da4-05bd-4da4-a2db-c8b7b594613b' User entered 'No (N)'	System	02 Sep 2020 06:43:18
	System	02 Sep 2020 06:43:18

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-01T23:43:16', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '7d1f8da4-05bd-4da4-a2db-c8b7b594613b' User entered '01 Sep 2020 23:43'	System	02 Sep 2020 06:43:18
	System	02 Sep 2020 06:43:18

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:01:05

US3682018

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	02 Sep 2020 23:57:42
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	02 Sep 2020 20:04:42
User entered 'Yes (Y)'	Susan Reed (b) (4)	02 Sep 2020 20:04:42
	(b) (4)	

US3682018

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '02 Sep 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	02 Sep 2020 20:04:42

US3682018

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Susan Reed (b) (4)	02 Sep 2020 23:57:42
User entered empty.	(b) (4)	
	Susan Reed (b) (4)	02 Sep 2020 20:04:42
	(b) (4)	

US3682018

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered empty.	Susan Reed (b) (4)	02 Sep 2020 20:04:42

US3682018

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Sep 2020 20:07:41

US3682018

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered '1'	System	09 Sep 2020 20:07:41

US3682018

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Sep 2020 20:07:55

US3682018

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '9 Sep 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Sep 2020 20:07:55

US3682018

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Sep 2020 20:07:55

US3682018

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered empty.	Susan Reed (b) (4)	09 Sep 2020 20:07:55

US3682018

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Sep 2020 20:08:01

US3682018

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'I'	System	09 Sep 2020 20:08:01

US3682018

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:15
User closed query 'Per CDM: Data is required. Please enter a response and complete form as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 12:29:20
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:58:33
Query 'Per CDM: Data is required. Please enter a response and complete form as appropriate.' answered with 'Updated per source documents' (Site from DM).	(b) (4) Mitchell Stern (b) (4)	23 Apr 2021 16:58:30
Signature has been broken.	(b) (4) Mitchell Stern (b) (4)	23 Apr 2021 16:57:39
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Mitchell Stern (b) (4)	23 Apr 2021 16:57:39
User opened query 'Per CDM: Data is required. Please enter a response and complete form as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 14:31:35
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 20:45:55
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 13:40:12
Query 'Data is required. Please complete.' answered with 'data error' (Site from System).	Susan Reed (b) (4)	15 Sep 2020 22:34:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	15 Sep 2020 22:34:50
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	15 Sep 2020 22:34:50
User entered empty; reason for change Data Entry Error	Susan Reed (b) (4)	15 Sep 2020 22:34:50
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4) System	15 Sep 2020 22:34:46
User entered 'Yes (Y)'	Susan Reed (b) (4)	15 Sep 2020 22:32:39

US3682018

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:15
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:58:33
Signature has been broken.	(b) (4)	
	Mitchell Stern (b) (4)	23 Apr 2021 16:57:39
	(b) (4)	
User entered '16 Sep 2020' reason for change: New Information	Mitchell Stern (b) (4)	23 Apr 2021 16:57:39
Data hard unlocked.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 20:45:55
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
	(b) (4)	
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Sep 2020 22:34:46
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	15 Sep 2020 22:34:46
User entered empty; reason for change Data Entry Error	Susan Reed (b) (4)	15 Sep 2020 22:34:46
	(b) (4)	
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Sep 2020 22:32:39
User entered '15 Sep 2020'	Susan Reed (b) (4)	15 Sep 2020 22:32:39
	(b) (4)	

US3682018

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:15
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:58:33
Signature has been broken.	(b) (4) Mitchell Stern (b) (4)	23 Apr 2021 16:57:39
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4) Mitchell Stern (b) (4)	23 Apr 2021 16:57:39
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 20:45:55
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered empty; reason for change Data Entry Error	(b) (4) Susan Reed (b) (4)	15 Sep 2020 22:34:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4)	15 Sep 2020 22:32:39

US3682018

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:15
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 20:45:55
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	15 Sep 2020 22:32:39

US3682018

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Yes (Y)'	Susan Reed (b) (4)	16 Sep 2020 23:10:04

US3682018

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'I'	System	16 Sep 2020 23:10:04

US3682018

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 20:16:53

US3682018

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '23 Sep 2020'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 20:16:53

US3682018

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Clinic (Clinic)'	(b) (4) Christopher Blades (b) (4) (b) (4)	23 Sep 2020 20:16:53

US3682018

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'VISIT2'	System	23 Sep 2020 20:16:53

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User accepted default value 'Pre-Dose (PREDOSE)'	Christopher Blades (b) (4)	23 Sep 2020 21:17:41
	(b) (4)	

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '23 Sep 2020'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '12:56'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered '23 Sep 2020 12:56'	System	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '97.9' F	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered 'Oral (Oral)'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered empty.	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '60'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'bpm'	System	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '16'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'breaths/min'	System	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '112'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'mmHg'	System	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '69'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'mmHg'	System	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User accepted default value 'Post-Dose (POSTDOSE)'	Christopher Blades (b) (4) (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '23 Sep 2020'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '13:59'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered '23 Sep 2020 13:59'	System	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '98.2' F	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered 'Oral (Oral)'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered empty.	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '67'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'bpm'	System	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '16'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'breaths/min'	System	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '110'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'mmHg'	System	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '74'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'mmHg'	System	23 Sep 2020 21:17:41

US3682018

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 20:37:00

US3682018

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '23 Sep 2020'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 20:37:00

US3682018

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 20:36:04

US3682018

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered empty.	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 20:36:04

US3682018

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered empty.	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 20:36:04

US3682018

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 20:36:04

US3682018

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '23 Sep 2020'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 20:36:04

US3682018

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '13:28'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 20:36:04

US3682018

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered '23 Sep 2020 13:28'	System	23 Sep 2020 20:36:04

US3682018

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Left Arm (LEFT ARM)'	(b) (4) Christopher Blades (b) (4)	23 Sep 2020 20:36:04

US3682018

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'ONCE'	System	23 Sep 2020 20:36:04

US3682018

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 20:36:04

US3682018

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:35:34

US3682018

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:35:34

US3682018

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '13:08'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:35:34

US3682018

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered '23 Sep 2020 13:08'	System	23 Sep 2020 22:35:34

US3682018

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:35:54

US3682018

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	23 Sep 2020 22:35:54

US3682018

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:35:54

US3682018

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '13:11'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:35:54

US3682018

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered '23 Sep 2020 13:11'	System	23 Sep 2020 22:35:54

US3682018

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	23 Sep 2020 22:35:54

US3682018

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:35:54

US3682018

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:35:54

US3682018

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered empty.	System	23 Sep 2020 22:35:54

US3682018

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4)	30 Sep 2020 22:52:29

US3682018

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered '1'	System	30 Sep 2020 22:52:29

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:01:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '10b04ed7-978a-43d9-9d4f-1b9a5d6fb9c9'	System	23 Sep 2020 21:01:42
User entered 'Yes (Y)'	System	23 Sep 2020 21:01:42

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:01:31', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '10b04ed7-978a-43d9-9d4f-1b9a5d6fb9c9' User entered '98.2'	System	23 Sep 2020 21:01:42
	System	23 Sep 2020 21:01:42

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:01:35', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '10b04ed7-978a-43d9-9d4f-1b9a5d6fb9c9'	System	23 Sep 2020 21:01:42
User entered 'No (N)'	System	23 Sep 2020 21:01:42

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:01:39', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '10b04ed7-978a-43d9-9d4f-1b9a5d6fb9c9' User entered '23 Sep 2020 14:01'	System	23 Sep 2020 21:01:42
	System	23 Sep 2020 21:01:42

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '23 Sep 2020 13:48'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '23 Sep 2020 16:18'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:40:41', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1d9daccb-3d5a-4dbd-8f70-5e1ca4edcd62' User entered 'Yes (Y)'	System	24 Sep 2020 06:41:18
	System	24 Sep 2020 06:41:18

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:41:04', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1d9daccb-3d5a-4dbd-8f70-5e1ca4edcd62' User entered '97.4'	System	24 Sep 2020 06:41:18
	System	24 Sep 2020 06:41:18

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:41:09', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1d9daccb-3d5a-4dbd-8f70-5e1ca4edcd62'	System	24 Sep 2020 06:41:18
User entered 'No (N)'	System	24 Sep 2020 06:41:18

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:41:15', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1d9daccb-3d5a-4dbd-8f70-5e1ca4edcd62' User entered '23 Sep 2020 23:41'	System	24 Sep 2020 06:41:18
	System	24 Sep 2020 06:41:18

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '23 Sep 2020 17:13'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 2'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:22:30', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '2c0591e7-5d76-47e3-b8f5-60589d2f2760'	System	25 Sep 2020 13:22:48
User entered 'Yes (Y)'	System	25 Sep 2020 13:22:48

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:22:37', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '2c0591e7-5d76-47e3-b8f5-60589d2f2760' User entered '96.7'	System	25 Sep 2020 13:22:48
	System	25 Sep 2020 13:22:48

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:22:40', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '2c0591e7-5d76-47e3-b8f5-60589d2f2760'	System	25 Sep 2020 13:22:48
User entered 'No (N)'	System	25 Sep 2020 13:22:48

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:22:45', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '2c0591e7-5d76-47e3-b8f5-60589d2f2760' User entered '25 Sep 2020 06:22'	System	25 Sep 2020 13:22:48
	System	25 Sep 2020 13:22:48

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 3'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:02', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '43c406d0-04be-4277-a3df-6d0aa12cd14d' User entered 'Yes (Y)'	System	26 Sep 2020 17:27:27
	System	26 Sep 2020 17:27:27

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:16', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '43c406d0-04be-4277-a3df-6d0aa12cd14d' User entered '98.1'	System	26 Sep 2020 17:27:27
	System	26 Sep 2020 17:27:27

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:19', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '43c406d0-04be-4277-a3df-6d0aa12cd14d' User entered 'No (N)'	System	26 Sep 2020 17:27:27
	System	26 Sep 2020 17:27:27

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:24', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '43c406d0-04be-4277-a3df-6d0aa12cd14d' User entered '26 Sep 2020 10:27'	System	26 Sep 2020 17:27:27
	System	26 Sep 2020 17:27:27

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 4'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:35:19', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '819eb913-5c98-484a-8358-5f21d4230986' User entered 'Yes (Y)'	System	27 Sep 2020 16:35:48
	System	27 Sep 2020 16:35:48

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:35:38', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '819eb913-5c98-484a-8358-5f21d4230986' User entered '98.2'	System	27 Sep 2020 16:35:48
	System	27 Sep 2020 16:35:48

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:35:41', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '819eb913-5c98-484a-8358-5f21d4230986'	System	27 Sep 2020 16:35:48
User entered 'No (N)'	System	27 Sep 2020 16:35:48

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:35:44', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '819eb913-5c98-484a-8358-5f21d4230986' User entered '27 Sep 2020 09:35'	System	27 Sep 2020 16:35:48
	System	27 Sep 2020 16:35:48

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 5'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 6'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:18:26', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '2f53741a-e334-4e32-ade6-b2d3aae31da4' User entered 'Yes (Y)'	System	29 Sep 2020 07:19:38
	System	29 Sep 2020 07:19:38

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:19:31', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '2f53741a-e334-4e32-ade6-b2d3aae31da4' User entered '97.7'	System	29 Sep 2020 07:19:38
	System	29 Sep 2020 07:19:38

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:19:34', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '2f53741a-e334-4e32-ade6-b2d3aae31da4'	System	29 Sep 2020 07:19:38
User entered 'No (N)'	System	29 Sep 2020 07:19:38

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:19:36', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '2f53741a-e334-4e32-ade6-b2d3aae31da4' User entered '29 Sep 2020 00:19'	System	29 Sep 2020 07:19:38
	System	29 Sep 2020 07:19:38

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 7'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:11:12', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '45755241-5de3-4e59-8519-0f2fe127b19e' User entered 'Yes (Y)'	System	30 Sep 2020 18:11:27
	System	30 Sep 2020 18:11:27

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:11:18', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '45755241-5de3-4e59-8519-0f2fe127b19e' User entered '97.3'	System	30 Sep 2020 18:11:27
	System	30 Sep 2020 18:11:27

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:11:23', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '45755241-5de3-4e59-8519-0f2fe127b19e' User entered 'No (N)'	System	30 Sep 2020 18:11:27
	System	30 Sep 2020 18:11:27

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:11:26', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '45755241-5de3-4e59-8519-0f2fe127b19e' User entered '30 Sep 2020 11:11'	System	30 Sep 2020 18:11:27
	System	30 Sep 2020 18:11:27

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:01:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'cd52cebb-79ca-41fc-93d8-8eda5879a191'	System	23 Sep 2020 21:02:16
User entered 'None (1)'	System	23 Sep 2020 21:02:16

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:01:56', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'cd52cebb-79ca-41fc-93d8-8eda5879a191' User entered 'No (N)'	System	23 Sep 2020 21:02:16
	System	23 Sep 2020 21:02:16

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:02:06', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'cd52cebb-79ca-41fc-93d8-8eda5879a191' User entered 'No (N)'	System	23 Sep 2020 21:02:16
	System	23 Sep 2020 21:02:16

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:02:09', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'cd52cebb-79ca-41fc-93d8-8eda5879a191'	System	23 Sep 2020 21:02:16
User entered 'None (1)'	System	23 Sep 2020 21:02:16

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:02:12', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'cd52cebb-79ca-41fc-93d8-8eda5879a191' User entered '23 Sep 2020 14:02'	System	23 Sep 2020 21:02:16
	System	23 Sep 2020 21:02:16

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '23 Sep 2020 13:48'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '23 Sep 2020 16:18'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:42:40', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '663de41f-cb84-4171-af8e-2d353b2b3d18'	System	24 Sep 2020 06:44:01
User entered 'None (1)'	System	24 Sep 2020 06:44:01

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:42:43', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '663de41f-cb84-4171-af8e-2d353b2b3d18' User entered 'No (N)'	System	24 Sep 2020 06:44:01
	System	24 Sep 2020 06:44:01

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:43:53', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '663de41f-cb84-4171-af8e-2d353b2b3d18' User entered 'No (N)'	System	24 Sep 2020 06:44:01
	System	24 Sep 2020 06:44:01

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:43:55', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '663de41f-cb84-4171-af8e-2d353b2b3d18'	System	24 Sep 2020 06:44:01
User entered 'None (1)'	System	24 Sep 2020 06:44:01

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:43:58', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '663de41f-cb84-4171-af8e-2d353b2b3d18' User entered '23 Sep 2020 23:43'	System	24 Sep 2020 06:44:01
	System	24 Sep 2020 06:44:01

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '23 Sep 2020 17:13'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 2'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:22:48', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'b90a04da-1f73-401b-a086-02d409ef53bf'	System	25 Sep 2020 13:23:00
User entered 'None (1)'	System	25 Sep 2020 13:23:00

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:22:51', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'b90a04da-1f73-401b-a086-02d409ef53bf'	System	25 Sep 2020 13:23:00
User entered 'No (N)'	System	25 Sep 2020 13:23:00

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:22:53', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'b90a04da-1f73-401b-a086-02d409ef53bf' User entered 'No (N)'	System	25 Sep 2020 13:23:00
	System	25 Sep 2020 13:23:00

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:22:55', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'b90a04da-1f73-401b-a086-02d409ef53bf'	System	25 Sep 2020 13:23:00
User entered 'None (1)'	System	25 Sep 2020 13:23:00

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:22:58', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'b90a04da-1f73-401b-a086-02d409ef53bf' User entered '25 Sep 2020 06:22'	System	25 Sep 2020 13:23:00
	System	25 Sep 2020 13:23:00

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 3'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:28', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '8a8f5fb0-7bfc-41f5-a72f-b146d96a0679'	System	26 Sep 2020 17:27:50
User entered 'None (1)'	System	26 Sep 2020 17:27:50

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:32', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '8a8f5fb0-7bfc-41f5-a72f-b146d96a0679'	System	26 Sep 2020 17:27:50
User entered 'No (N)'	System	26 Sep 2020 17:27:50

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:36', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '8a8f5fb0-7bfc-41f5-a72f-b146d96a0679'	System	26 Sep 2020 17:27:50
User entered 'No (N)'	System	26 Sep 2020 17:27:50

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:41', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '8a8f5fb0-7bfc-41f5-a72f-b146d96a0679'	System	26 Sep 2020 17:27:50
User entered 'None (1)'	System	26 Sep 2020 17:27:50

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:44', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '8a8f5fb0-7bfc-41f5-a72f-b146d96a0679'	System	26 Sep 2020 17:27:50
User entered '26 Sep 2020 10:27'	System	26 Sep 2020 17:27:50

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 4'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:35:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'ea3577e0-3871-41b6-81ee-90e6085cc138'	System	27 Sep 2020 16:36:00
User entered 'None (1)'	System	27 Sep 2020 16:36:00

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:35:50', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'ea3577e0-3871-41b6-81ee-90e6085cc138' User entered 'No (N)'	System	27 Sep 2020 16:36:00
	System	27 Sep 2020 16:36:00

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:35:52', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'ea3577e0-3871-41b6-81ee-90e6085cc138' User entered 'No (N)'	System	27 Sep 2020 16:36:00
	System	27 Sep 2020 16:36:00

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:35:54', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'ea3577e0-3871-41b6-81ee-90e6085cc138'	System	27 Sep 2020 16:36:00
User entered 'None (1)'	System	27 Sep 2020 16:36:00

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:35:57', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'ea3577e0-3871-41b6-81ee-90e6085cc138' User entered '27 Sep 2020 09:35'	System	27 Sep 2020 16:36:00
	System	27 Sep 2020 16:36:00

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 5'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 6'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:19:41', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0732cb97-74b1-4134-8f99-faf035d195cf'	System	29 Sep 2020 07:19:53
User entered 'None (1)'	System	29 Sep 2020 07:19:53

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:19:43', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0732cb97-74b1-4134-8f99-faf035d195cf' User entered 'No (N)'	System	29 Sep 2020 07:19:53
	System	29 Sep 2020 07:19:53

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:19:46', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0732cb97-74b1-4134-8f99-faf035d195cf' User entered 'No (N)'	System	29 Sep 2020 07:19:53
	System	29 Sep 2020 07:19:53

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:19:48', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0732cb97-74b1-4134-8f99-faf035d195cf'	System	29 Sep 2020 07:19:53
User entered 'None (1)'	System	29 Sep 2020 07:19:53

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:19:51', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0732cb97-74b1-4134-8f99-faf035d195cf' User entered '29 Sep 2020 00:19'	System	29 Sep 2020 07:19:53
	System	29 Sep 2020 07:19:53

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 7'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:14:14', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '8f8645d0-b733-4302-8a79-1e1d6278b15a' User entered 'None (1)'	System	30 Sep 2020 18:14:26
	System	30 Sep 2020 18:14:26

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:14:16', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '8f8645d0-b733-4302-8a79-1e1d6278b15a' User entered 'No (N)'	System	30 Sep 2020 18:14:26
	System	30 Sep 2020 18:14:26

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:14:18', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '8f8645d0-b733-4302-8a79-1e1d6278b15a' User entered 'No (N)'	System	30 Sep 2020 18:14:26
	System	30 Sep 2020 18:14:26

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:14:19', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '8f8645d0-b733-4302-8a79-1e1d6278b15a' User entered 'None (1)'	System	30 Sep 2020 18:14:26
	System	30 Sep 2020 18:14:26

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:14:21', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '8f8645d0-b733-4302-8a79-1e1d6278b15a' User entered '30 Sep 2020 11:14'	System	30 Sep 2020 18:14:26
	System	30 Sep 2020 18:14:26

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:02:19', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '6b01cf7b-789d-4a50-b9d9-f02dac3c5f35'	System	23 Sep 2020 21:02:41
User entered 'None (0)'	System	23 Sep 2020 21:02:41

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:02:21', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '6b01cf7b-789d-4a50-b9d9-f02dac3c5f35'	System	23 Sep 2020 21:02:41
User entered 'None (0)'	System	23 Sep 2020 21:02:41

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:02:23', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '6b01cf7b-789d-4a50-b9d9-f02dac3c5f35' User entered 'None (0)'	System	23 Sep 2020 21:02:41
	System	23 Sep 2020 21:02:41

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:02:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '6b01cf7b-789d-4a50-b9d9-f02dac3c5f35' User entered 'None (0)'	System	23 Sep 2020 21:02:41
	System	23 Sep 2020 21:02:41

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:02:26', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '6b01cf7b-789d-4a50-b9d9-f02dac3c5f35' User entered 'None (0)'	System	23 Sep 2020 21:02:41
	System	23 Sep 2020 21:02:41

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:02:28', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '6b01cf7b-789d-4a50-b9d9-f02dac3c5f35' User entered 'None (0)'	System	23 Sep 2020 21:02:41
	System	23 Sep 2020 21:02:41

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:02:35', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '6b01cf7b-789d-4a50-b9d9-f02dac3c5f35'	System	23 Sep 2020 21:02:41
User entered 'No (N)'	System	23 Sep 2020 21:02:41

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T14:02:37', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '6b01cf7b-789d-4a50-b9d9-f02dac3c5f35'	System	23 Sep 2020 21:02:41
User entered '23 Sep 2020 14:02'	System	23 Sep 2020 21:02:41

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '23 Sep 2020 13:48'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '23 Sep 2020 16:18'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:44:02', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1455819f-be9c-44aa-9bb2-c8c8b9f72dbb' User entered 'None (0)'	System	24 Sep 2020 06:44:24
	System	24 Sep 2020 06:44:24

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:44:03', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1455819f-be9c-44aa-9bb2-c8c8b9f72dbb' User entered 'None (0)'	System	24 Sep 2020 06:44:24
	System	24 Sep 2020 06:44:24

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:44:05', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1455819f-be9c-44aa-9bb2-c8c8b9f72dbb' User entered 'None (0)'	System	24 Sep 2020 06:44:24
	System	24 Sep 2020 06:44:24

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:44:06', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1455819f-be9c-44aa-9bb2-c8c8b9f72dbb' User entered 'None (0)'	System	24 Sep 2020 06:44:24
	System	24 Sep 2020 06:44:24

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:44:08', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1455819f-be9c-44aa-9bb2-c8c8b9f72dbb' User entered 'None (0)'	System	24 Sep 2020 06:44:24
	System	24 Sep 2020 06:44:24

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:44:09', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1455819f-be9c-44aa-9bb2-c8c8b9f72dbb' User entered 'None (0)'	System	24 Sep 2020 06:44:24
	System	24 Sep 2020 06:44:24

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:44:15', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1455819f-be9c-44aa-9bb2-c8c8b9f72dbb' User entered 'No (N)'	System	24 Sep 2020 06:44:24
	System	24 Sep 2020 06:44:24

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-23T23:44:19', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1455819f-be9c-44aa-9bb2-c8c8b9f72dbb' User entered '23 Sep 2020 23:44'	System	24 Sep 2020 06:44:24
	System	24 Sep 2020 06:44:24

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '23 Sep 2020 17:13'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 2'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:23:04', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1e352cff-463f-4141-9d95-c9ad215dc38b' User entered 'None (0)'	System	25 Sep 2020 13:23:20
	System	25 Sep 2020 13:23:20

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:23:05', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1e352cff-463f-4141-9d95-c9ad215dc38b' User entered 'None (0)'	System	25 Sep 2020 13:23:20
	System	25 Sep 2020 13:23:20

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:23:07', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1e352cff-463f-4141-9d95-c9ad215dc38b' User entered 'None (0)'	System	25 Sep 2020 13:23:20
	System	25 Sep 2020 13:23:20

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:23:08', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1e352cff-463f-4141-9d95-c9ad215dc38b' User entered 'None (0)'	System	25 Sep 2020 13:23:20
	System	25 Sep 2020 13:23:20

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:23:10', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1e352cff-463f-4141-9d95-c9ad215dc38b' User entered 'None (0)'	System	25 Sep 2020 13:23:20
	System	25 Sep 2020 13:23:20

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:23:11', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1e352cff-463f-4141-9d95-c9ad215dc38b' User entered 'None (0)'	System	25 Sep 2020 13:23:20
	System	25 Sep 2020 13:23:20

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:23:16', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1e352cff-463f-4141-9d95-c9ad215dc38b' User entered 'No (N)'	System	25 Sep 2020 13:23:20
	System	25 Sep 2020 13:23:20

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-25T06:23:18', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '1e352cff-463f-4141-9d95-c9ad215dc38b' User entered '25 Sep 2020 06:23'	System	25 Sep 2020 13:23:20
	System	25 Sep 2020 13:23:20

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 3'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:49', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9b13b520-e7b9-4b28-b1ee-aa02216e0dd1' User entered 'None (0)'	System	26 Sep 2020 17:28:13
	System	26 Sep 2020 17:28:13

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:51', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9b13b520-e7b9-4b28-b1ee-aa02216e0dd1' User entered 'None (0)'	System	26 Sep 2020 17:28:13
	System	26 Sep 2020 17:28:13

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:53', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9b13b520-e7b9-4b28-b1ee-aa02216e0dd1' User entered 'None (0)'	System	26 Sep 2020 17:28:13
	System	26 Sep 2020 17:28:13

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:56', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9b13b520-e7b9-4b28-b1ee-aa02216e0dd1' User entered 'None (0)'	System	26 Sep 2020 17:28:13
	System	26 Sep 2020 17:28:13

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:57', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9b13b520-e7b9-4b28-b1ee-aa02216e0dd1' User entered 'None (0)'	System	26 Sep 2020 17:28:13
	System	26 Sep 2020 17:28:13

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:27:59', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9b13b520-e7b9-4b28-b1ee-aa02216e0dd1' User entered 'None (0)'	System	26 Sep 2020 17:28:13
	System	26 Sep 2020 17:28:13

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:28:06', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9b13b520-e7b9-4b28-b1ee-aa02216e0dd1' User entered 'No (N)'	System	26 Sep 2020 17:28:13
	System	26 Sep 2020 17:28:13

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-26T10:28:11', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9b13b520-e7b9-4b28-b1ee-aa02216e0dd1' User entered '26 Sep 2020 10:28'	System	26 Sep 2020 17:28:13
	System	26 Sep 2020 17:28:13

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 4'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:36:01', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'cb2d2d34-c544-4c9b-8d60-5d807e91a5ed' User entered 'None (0)'	System	27 Sep 2020 16:36:17
	System	27 Sep 2020 16:36:17

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:36:03', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'cb2d2d34-c544-4c9b-8d60-5d807e91a5ed' User entered 'None (0)'	System	27 Sep 2020 16:36:17
	System	27 Sep 2020 16:36:17

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:36:04', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'cb2d2d34-c544-4c9b-8d60-5d807e91a5ed' User entered 'None (0)'	System	27 Sep 2020 16:36:17
	System	27 Sep 2020 16:36:17

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:36:06', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'cb2d2d34-c544-4c9b-8d60-5d807e91a5ed' User entered 'None (0)'	System	27 Sep 2020 16:36:17
	System	27 Sep 2020 16:36:17

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:36:07', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'cb2d2d34-c544-4c9b-8d60-5d807e91a5ed' User entered 'None (0)'	System	27 Sep 2020 16:36:17
	System	27 Sep 2020 16:36:17

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:36:09', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'cb2d2d34-c544-4c9b-8d60-5d807e91a5ed' User entered 'None (0)'	System	27 Sep 2020 16:36:17
	System	27 Sep 2020 16:36:17

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:36:11', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'cb2d2d34-c544-4c9b-8d60-5d807e91a5ed' User entered 'No (N)'	System	27 Sep 2020 16:36:17
	System	27 Sep 2020 16:36:17

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-27T09:36:14', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'cb2d2d34-c544-4c9b-8d60-5d807e91a5ed' User entered '27 Sep 2020 09:36'	System	27 Sep 2020 16:36:17
	System	27 Sep 2020 16:36:17

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 5'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 6'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:19:54', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'b9086059-1604-4fca-a9f8-8fb01bb05b52' User entered 'None (0)'	System	29 Sep 2020 07:20:12
	System	29 Sep 2020 07:20:12

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:19:56', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'b9086059-1604-4fca-a9f8-8fb01bb05b52' User entered 'None (0)'	System	29 Sep 2020 07:20:12
	System	29 Sep 2020 07:20:12

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:19:58', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'b9086059-1604-4fca-a9f8-8fb01bb05b52' User entered 'None (0)'	System	29 Sep 2020 07:20:12
	System	29 Sep 2020 07:20:12

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:20:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'b9086059-1604-4fca-a9f8-8fb01bb05b52'	System	29 Sep 2020 07:20:12
User entered 'None (0)'	System	29 Sep 2020 07:20:12

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:20:02', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'b9086059-1604-4fca-a9f8-8fb01bb05b52' User entered 'None (0)'	System	29 Sep 2020 07:20:12
	System	29 Sep 2020 07:20:12

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:20:04', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'b9086059-1604-4fca-a9f8-8fb01bb05b52'	System	29 Sep 2020 07:20:12
User entered 'None (0)'	System	29 Sep 2020 07:20:12

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:20:07', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'b9086059-1604-4fca-a9f8-8fb01bb05b52'	System	29 Sep 2020 07:20:12
User entered 'No (N)'	System	29 Sep 2020 07:20:12

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-29T00:20:09', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'b9086059-1604-4fca-a9f8-8fb01bb05b52' User entered '29 Sep 2020 00:20'	System	29 Sep 2020 07:20:12
	System	29 Sep 2020 07:20:12

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	23 Sep 2020 20:36:04
User entered 'Day 7'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:14:24', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '04dec3b1-419f-4bf7-9e42-8dac2c61041f' User entered 'None (0)'	System	30 Sep 2020 18:14:38
	System	30 Sep 2020 18:14:38

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:14:26', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '04dec3b1-419f-4bf7-9e42-8dac2c61041f' User entered 'None (0)'	System	30 Sep 2020 18:14:38
	System	30 Sep 2020 18:14:38

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:14:27', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '04dec3b1-419f-4bf7-9e42-8dac2c61041f' User entered 'None (0)'	System	30 Sep 2020 18:14:38
	System	30 Sep 2020 18:14:38

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:14:28', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '04dec3b1-419f-4bf7-9e42-8dac2c61041f' User entered 'None (0)'	System	30 Sep 2020 18:14:38
	System	30 Sep 2020 18:14:38

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:14:30', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '04dec3b1-419f-4bf7-9e42-8dac2c61041f' User entered 'None (0)'	System	30 Sep 2020 18:14:38
	System	30 Sep 2020 18:14:38

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:14:31', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '04dec3b1-419f-4bf7-9e42-8dac2c61041f' User entered 'None (0)'	System	30 Sep 2020 18:14:38
	System	30 Sep 2020 18:14:38

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:14:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '04dec3b1-419f-4bf7-9e42-8dac2c61041f' User entered 'No (N)'	System	30 Sep 2020 18:14:38
	System	30 Sep 2020 18:14:38

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-09-30T11:14:35', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '04dec3b1-419f-4bf7-9e42-8dac2c61041f' User entered '30 Sep 2020 11:14'	System	30 Sep 2020 18:14:38
	System	30 Sep 2020 18:14:38

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 20:36:04

US3682018

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 20:36:04

US3682018

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	30 Sep 2020 22:52:42

US3682018

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered '30 Sep 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	30 Sep 2020 22:52:42

US3682018

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4)	30 Sep 2020 22:52:42

US3682018

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered empty.	Susan Reed (b) (4)	30 Sep 2020 22:52:42

US3682018

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:10:18
User entered 'Yes (Y)'	Susan Reed (b) (4)	07 Oct 2020 20:08:09

US3682018

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'I'	System	07 Oct 2020 20:08:09

US3682018

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	07 Oct 2020 20:08:39

US3682018

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '7 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	07 Oct 2020 20:08:39

US3682018

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4)	07 Oct 2020 20:08:39

US3682018

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered empty.	Susan Reed (b) (4)	07 Oct 2020 20:08:39

US3682018

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	07 Oct 2020 20:08:46

US3682018

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'I'	System	07 Oct 2020 20:08:46

US3682018

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	14 Oct 2020 19:33:11

US3682018

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered '14 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	14 Oct 2020 19:33:11

US3682018

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4)	14 Oct 2020 19:33:11

US3682018

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	14 Oct 2020 19:33:11

US3682018

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:57:52
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	14 Oct 2020 19:33:15

US3682018

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'I'	System	14 Oct 2020 19:33:15

US3682018

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:25:34

US3682018

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '20 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:25:34

US3682018

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered 'Clinic (Clinic)'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:25:34

US3682018

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'VISIT3'	System	21 Oct 2020 00:25:34

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '20 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '15:27'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered '20 Oct 2020 15:27'	System	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '98.1' F	Schuyler Thomas (b) (4)	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered 'Oral (Oral)'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '97'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'bpm'	System	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '18'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'breaths/min'	System	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '111'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'mmHg'	System	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '70'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'mmHg'	System	21 Oct 2020 00:27:09

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26

US3682018

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26

US3682018

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:25:46

US3682018

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '20 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:25:46

US3682018

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 00:24:35

US3682018

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 00:24:35

US3682018

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered '15:51'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 00:24:35

US3682018

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered '20 Oct 2020 15:51'	System	21 Oct 2020 00:24:35

US3682018

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:58:34
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	21 Oct 2020 00:25:22

US3682018

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:26
User entered 'I'	System	21 Oct 2020 00:25:22

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 64'	System	26 Aug 2020 21:01:05

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-10-28T17:55:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a7a212c1-1665-4df1-8977-d20c2a2f5a1f' User entered 'No (N)'	System	29 Oct 2020 00:55:20
	System	29 Oct 2020 00:55:20

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-10-28T17:55:03', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a7a212c1-1665-4df1-8977-d20c2a2f5a1f' User entered 'No (N)'	System	29 Oct 2020 00:55:20
	System	29 Oct 2020 00:55:20

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-10-28T17:55:17', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a7a212c1-1665-4df1-8977-d20c2a2f5a1f' User entered '28 Oct 2020 17:55:17'	System	29 Oct 2020 00:55:20
	System	29 Oct 2020 00:55:20

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 21:01:05

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 71'	System	26 Aug 2020 21:01:05

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-11-04T14:45:01', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9b12f204-e14f-4cf9-83e9-21830494c3ed'	System	04 Nov 2020 22:45:12
User entered 'No (N)'	System	04 Nov 2020 22:45:12

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-11-04T14:45:06', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9b12f204-e14f-4cf9-83e9-21830494c3ed'	System	04 Nov 2020 22:45:12
User entered 'No (N)'	System	04 Nov 2020 22:45:12

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-11-04T14:45:09', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '9b12f204-e14f-4cf9-83e9-21830494c3ed' User entered '04 Nov 2020 14:45:09'	System	04 Nov 2020 22:45:12
	System	04 Nov 2020 22:45:12

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 21:01:05

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered 'Day 78'	System	26 Aug 2020 21:01:05

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-11-09T00:01:34', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0fd96d24-7c81-4b5e-bd9d-15c9bd32c074'	System	09 Nov 2020 08:01:44
User entered 'No (N)'	System	09 Nov 2020 08:01:44

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-11-09T00:01:37', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0fd96d24-7c81-4b5e-bd9d-15c9bd32c074'	System	09 Nov 2020 08:01:44
User entered 'No (N)'	System	09 Nov 2020 08:01:44

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-11-09T00:01:41', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0fd96d24-7c81-4b5e-bd9d-15c9bd32c074' User entered '09 Nov 2020 00:01:41'	System	09 Nov 2020 08:01:44
	System	09 Nov 2020 08:01:44

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 21:01:05

US3682018

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:30:52
Data entry locked.	System	26 Aug 2020 21:01:05
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 21:01:05

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-11-23T00:11:32', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a45755c5-9242-437e-bf8f-661708bffda8'	System	23 Nov 2020 08:11:46
User entered 'No (N)'	System	23 Nov 2020 08:11:46

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-11-23T00:11:36', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a45755c5-9242-437e-bf8f-661708bffda8'	System	23 Nov 2020 08:11:46
User entered 'No (N)'	System	23 Nov 2020 08:11:46

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-11-23T00:11:43', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a45755c5-9242-437e-bf8f-661708bffda8' User entered '23 Nov 2020 00:11:43'	System	23 Nov 2020 08:11:46
	System	23 Nov 2020 08:11:46

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-11-27T00:02:13', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0b67a0d1-7a9a-4efb-877b-29d25a223898'	System	27 Nov 2020 08:02:31
User entered 'No (N)'	System	27 Nov 2020 08:02:31

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-11-27T00:02:17', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0b67a0d1-7a9a-4efb-877b-29d25a223898'	System	27 Nov 2020 08:02:31
User entered 'No (N)'	System	27 Nov 2020 08:02:31

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-11-27T00:02:28', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0b67a0d1-7a9a-4efb-877b-29d25a223898' User entered '27 Nov 2020 00:02:28'	System	27 Nov 2020 08:02:31
	System	27 Nov 2020 08:02:31

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-04T00:04:13', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a34e56ef-d2c2-4b5b-a885-b89769f29d1f' User entered 'No (N)'	System	04 Dec 2020 08:04:28
	System	04 Dec 2020 08:04:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-04T00:04:22', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a34e56ef-d2c2-4b5b-a885-b89769f29d1f'	System	04 Dec 2020 08:04:28
User entered 'No (N)'	System	04 Dec 2020 08:04:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-04T00:04:26', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a34e56ef-d2c2-4b5b-a885-b89769f29d1f' User entered '04 Dec 2020 00:04:26'	System	04 Dec 2020 08:04:28
	System	04 Dec 2020 08:04:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:33:53', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1' User entered 'Yes (Y)'	System	11 Dec 2020 08:35:13
	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered 'Yes (Y)'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:08', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:14', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1' User entered 'Yes (Y)'	System	11 Dec 2020 08:35:13
	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1' User entered '1'	System	11 Dec 2020 08:35:13
	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '1'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '0'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '0'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '0'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '1'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '1'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '1'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '1'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '0'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '0'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '0'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1' User entered '1'	System	11 Dec 2020 08:35:13
	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '0'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '0'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '0'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:33', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered '1'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:38', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:49', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1' User entered 'Yes (Y)'	System	11 Dec 2020 08:35:13
	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:34:55', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1'	System	11 Dec 2020 08:35:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-11T00:35:02', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '22075e5c-17c3-4d2e-9a0a-bc690d6d1dd1' User entered '11 Dec 2020 00:35:02'	System	11 Dec 2020 08:35:13
	System	11 Dec 2020 08:35:13

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:06:58', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered 'Yes (Y)'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:12', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e'	System	20 Dec 2020 20:08:28
User entered 'No (N)'	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:18', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered 'Yes (Y)'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '1'	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '1'	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '1'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '0'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '0'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '1'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '1'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '1'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '1'	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '0'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '0'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '0'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '1'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '0'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '0'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '0'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '1'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:07:58', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e'	System	20 Dec 2020 20:08:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:08:06', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered 'No (N)'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-20T12:08:17', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '333012a2-7fb9-4b6a-a04a-d4e390b6610e' User entered '20 Dec 2020 12:08:17'	System	20 Dec 2020 20:08:28
	System	20 Dec 2020 20:08:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-26T09:48:44', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd3122af4-49a6-4b9f-a79f-3b229db1655c'	System	26 Dec 2020 14:49:09
User entered 'Yes (Y)'	System	26 Dec 2020 14:49:09

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-26T09:48:51', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd3122af4-49a6-4b9f-a79f-3b229db1655c' User entered 'No (N)'	System	26 Dec 2020 14:49:09
	System	26 Dec 2020 14:49:09

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-26T09:48:57', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd3122af4-49a6-4b9f-a79f-3b229db1655c' User entered 'No (N)'	System	26 Dec 2020 14:49:09
	System	26 Dec 2020 14:49:09

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-26T09:49:03', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd3122af4-49a6-4b9f-a79f-3b229db1655c' User entered 'No (N)'	System	26 Dec 2020 14:49:09
	System	26 Dec 2020 14:49:09

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2020-12-26T09:49:07', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd3122af4-49a6-4b9f-a79f-3b229db1655c' User entered '26 Dec 2020 09:49:07'	System	26 Dec 2020 14:49:09
	System	26 Dec 2020 14:49:09

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-01T00:04:09', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'fe5868f4-7f34-4ee5-9e2e-deeb954a9527'	System	01 Jan 2021 08:04:36
User entered 'No (N)'	System	01 Jan 2021 08:04:36

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-01T00:04:27', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'fe5868f4-7f34-4ee5-9e2e-deeb954a9527'	System	01 Jan 2021 08:04:36
User entered 'No (N)'	System	01 Jan 2021 08:04:36

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-01T00:04:34', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'fe5868f4-7f34-4ee5-9e2e-deeb954a9527' User entered '01 Jan 2021 00:04:34'	System	01 Jan 2021 08:04:36
	System	01 Jan 2021 08:04:36

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-10T16:54:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '8f687c5e-499e-48d9-ac50-450a60b7452f' User entered 'No (N)'	System	11 Jan 2021 00:54:58
	System	11 Jan 2021 00:54:58

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-10T16:54:51', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '8f687c5e-499e-48d9-ac50-450a60b7452f'	System	11 Jan 2021 00:54:58
User entered 'No (N)'	System	11 Jan 2021 00:54:58

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-10T16:54:54', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '8f687c5e-499e-48d9-ac50-450a60b7452f' User entered '10 Jan 2021 16:54:54'	System	11 Jan 2021 00:54:58
	System	11 Jan 2021 00:54:58

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-18T17:59:14', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '17f16485-11e8-4385-9edf-302ec23f687f' User entered 'No (N)'	System	19 Jan 2021 01:59:28
	System	19 Jan 2021 01:59:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-18T17:59:23', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '17f16485-11e8-4385-9edf-302ec23f687f'	System	19 Jan 2021 01:59:28
User entered 'No (N)'	System	19 Jan 2021 01:59:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-18T17:59:26', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '17f16485-11e8-4385-9edf-302ec23f687f' User entered '18 Jan 2021 17:59:26'	System	19 Jan 2021 01:59:28
	System	19 Jan 2021 01:59:28

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-24T12:58:31', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'e025a962-13aa-4fac-a073-e3e327362746'	System	24 Jan 2021 20:58:39
User entered 'No (N)'	System	24 Jan 2021 20:58:39

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-24T12:58:35', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'e025a962-13aa-4fac-a073-e3e327362746'	System	24 Jan 2021 20:58:39
User entered 'No (N)'	System	24 Jan 2021 20:58:39

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-24T12:58:38', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'e025a962-13aa-4fac-a073-e3e327362746' User entered '24 Jan 2021 12:58:38'	System	24 Jan 2021 20:58:39

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:20:30', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered 'Yes (Y)'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:20:38', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered 'No (N)'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:20:47', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered 'Yes (Y)'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2' User entered '0'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered '1'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered '0'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered '0'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered '0'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered '1'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2' User entered '1'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered '1'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered '1'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered '0'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered '0'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered '0'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2' User entered '0'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered '0'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered '0'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2' User entered '0'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:25', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered '0'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:37', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:44', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2'	System	29 Jan 2021 17:22:01
User entered 'No (N)'	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-01-29T09:21:50', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '034b90ca-1ddf-49a1-b65a-5be8e4e2f3d2' User entered '29 Jan 2021 09:21:50'	System	29 Jan 2021 17:22:01
	System	29 Jan 2021 17:22:01

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-08T12:28:59', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'ce881d89-6a73-468e-9abc-6d22f9a50db1' User entered 'No (N)'	System	08 Feb 2021 20:29:10
	System	08 Feb 2021 20:29:10

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-08T12:29:03', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'ce881d89-6a73-468e-9abc-6d22f9a50db1' User entered 'No (N)'	System	08 Feb 2021 20:29:10
	System	08 Feb 2021 20:29:10

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-08T12:29:06', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'ce881d89-6a73-468e-9abc-6d22f9a50db1' User entered '08 Feb 2021 12:29:06'	System	08 Feb 2021 20:29:10

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-12T00:11:09', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0228aaab-cca5-421f-878c-5719af455954'	System	12 Feb 2021 08:11:17
User entered 'No (N)'	System	12 Feb 2021 08:11:17

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-12T00:11:12', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0228aaab-cca5-421f-878c-5719af455954'	System	12 Feb 2021 08:11:17
User entered 'No (N)'	System	12 Feb 2021 08:11:17

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-12T00:11:15', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0228aaab-cca5-421f-878c-5719af455954'	System	12 Feb 2021 08:11:17
User entered '12 Feb 2021 00:11:15'	System	12 Feb 2021 08:11:17

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-19T00:05:57', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0eff8ded-e79c-4144-b16c-bdec0a1f33e'	System	19 Feb 2021 08:06:09
User entered 'No (N)'	System	19 Feb 2021 08:06:09

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-19T00:06:01', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0eff8ded-e79c-4144-b16c-bdec0a1f33e'	System	19 Feb 2021 08:06:09
User entered 'No (N)'	System	19 Feb 2021 08:06:09

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-19T00:06:04', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '0eff8ded-e79c-4144-b16c-bdec0a1f33e' User entered '19 Feb 2021 00:06:04'	System	19 Feb 2021 08:06:09
	System	19 Feb 2021 08:06:09

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-28T13:31:51-08:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '6a4904a7-6e01-41fd-963b-5bd786ccb84e' User entered 'No (N)'	System	28 Feb 2021 21:32:00
	System	28 Feb 2021 21:32:00

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-28T13:31:54-08:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '6a4904a7-6e01-41fd-963b-5bd786ccb84e' User entered 'No (N)'	System	28 Feb 2021 21:32:00
	System	28 Feb 2021 21:32:00

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-28T13:31:57-08:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '6a4904a7-6e01-41fd-963b-5bd786ccb84e' User entered '28 Feb 2021 13:31:57'	System	28 Feb 2021 21:32:00
	System	28 Feb 2021 21:32:00

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-03-07T12:01:02-08:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a9327739-f104-49c3-b117-bcbf63b34bdf'	System	07 Mar 2021 20:01:17
User entered 'No (N)'	System	07 Mar 2021 20:01:17

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-03-07T12:01:07-08:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a9327739-f104-49c3-b117-bcbf63b34bdf'	System	07 Mar 2021 20:01:17
User entered 'No (N)'	System	07 Mar 2021 20:01:17

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-03-07T12:01:10-08:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'a9327739-f104-49c3-b117-bcbf63b34bdf' User entered '07 Mar 2021 12:01:10'	System	07 Mar 2021 20:01:17
	System	07 Mar 2021 20:01:17

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-03-14T15:29:07-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '52446554-3434-47d5-9ae3-690eedb4f588'	System	14 Mar 2021 22:29:19
User entered 'No (N)'	System	14 Mar 2021 22:29:19

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-03-14T15:29:14-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '52446554-3434-47d5-9ae3-690eedb4f588'	System	14 Mar 2021 22:29:19
User entered 'No (N)'	System	14 Mar 2021 22:29:19

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-03-14T15:29:17-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '52446554-3434-47d5-9ae3-690eedb4f588' User entered '14 Mar 2021 15:29:17'	System	14 Mar 2021 22:29:19
	System	14 Mar 2021 22:29:19

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-03-19T00:35:02-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'fba0b4a3-9d09-4f61-a454-83bfef86270'	System	19 Mar 2021 07:35:16
User entered 'No (N)'	System	19 Mar 2021 07:35:16

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-03-19T00:35:05-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'fba0b4a3-9d09-4f61-a454-83bfef86270'	System	19 Mar 2021 07:35:16
User entered 'No (N)'	System	19 Mar 2021 07:35:16

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-03-19T00:35:11-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'fba0b4a3-9d09-4f61-a454-83bfefd86270' User entered '19 Mar 2021 00:35:11'	System	19 Mar 2021 07:35:16
	System	19 Mar 2021 07:35:16

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-03-26T00:02:21-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd6ef801a-604a-45d7-8442-36666736569b'	System	26 Mar 2021 07:02:29
User entered 'No (N)'	System	26 Mar 2021 07:02:29

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-03-26T00:02:24-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd6ef801a-604a-45d7-8442-36666736569b'	System	26 Mar 2021 07:02:29
User entered 'No (N)'	System	26 Mar 2021 07:02:29

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-03-26T00:02:27-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'd6ef801a-604a-45d7-8442-36666736569b' User entered '26 Mar 2021 00:02:27'	System	26 Mar 2021 07:02:29
	System	26 Mar 2021 07:02:29

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-02T17:17:31-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'f151d45c-800f-4b65-aed1-a6d73c1afaa6'	System	03 Apr 2021 00:17:51
User entered 'Yes (Y)'	System	03 Apr 2021 00:17:51

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-02T17:17:36-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'f151d45c-800f-4b65-aed1-a6d73c1afaa6'	System	03 Apr 2021 00:17:51
User entered 'No (N)'	System	03 Apr 2021 00:17:51

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-02T17:17:40-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'f151d45c-800f-4b65-aed1-a6d73c1afaa6'	System	03 Apr 2021 00:17:51
User entered 'No (N)'	System	03 Apr 2021 00:17:51

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-02T17:17:46-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'f151d45c-800f-4b65-aed1-a6d73c1afaa6'	System	03 Apr 2021 00:17:51
User entered 'No (N)'	System	03 Apr 2021 00:17:51

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-02T17:17:49-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'f151d45c-800f-4b65-aed1-a6d73c1afaa6'	System	03 Apr 2021 00:17:51
User entered '02 Apr 2021 17:17:49'	System	03 Apr 2021 00:17:51

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-09T00:02:15-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '31254c72-02e1-4ad3-8bdf-8ee5764fd4ec'	System	09 Apr 2021 07:02:24
User entered 'No (N)'	System	09 Apr 2021 07:02:24

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-09T00:02:17-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '31254c72-02e1-4ad3-8bdf-8ee5764fd4ec'	System	09 Apr 2021 07:02:24
User entered 'No (N)'	System	09 Apr 2021 07:02:24

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-09T00:02:20-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '31254c72-02e1-4ad3-8bdf-8ee5764fd4ec' User entered '09 Apr 2021 00:02:20'	System	09 Apr 2021 07:02:24
	System	09 Apr 2021 07:02:24

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-19T17:59:23-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '3df51fa4-a56e-4fbe-bfd6-9b7d94a1f84d' User entered 'No (N)'	System	20 Apr 2021 00:59:33
	System	20 Apr 2021 00:59:33

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-19T17:59:27-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '3df51fa4-a56e-4fbe-bfd6-9b7d94a1f84d' User entered 'No (N)'	System	20 Apr 2021 00:59:33
	System	20 Apr 2021 00:59:33

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-19T17:59:30-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '3df51fa4-a56e-4fbe-bfd6-9b7d94a1f84d' User entered '19 Apr 2021 17:59:30'	System	20 Apr 2021 00:59:33
	System	20 Apr 2021 00:59:33

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-26T22:13:56-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'eed259fa-7253-4c38-b77f-85dc6bf88e78'	System	27 Apr 2021 05:14:06
User entered 'No (N)'	System	27 Apr 2021 05:14:06

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-26T22:13:58-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'eed259fa-7253-4c38-b77f-85dc6bf88e78'	System	27 Apr 2021 05:14:06
User entered 'No (N)'	System	27 Apr 2021 05:14:06

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-26T22:14:00-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: 'eed259fa-7253-4c38-b77f-85dc6bf88e78'	System	27 Apr 2021 05:14:06
User entered '26 Apr 2021 22:14:00'	System	27 Apr 2021 05:14:06

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-30T00:03:28-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '72eaae88-7218-4456-9dd0-0d20d933c692'	System	30 Apr 2021 07:03:36
User entered 'No (N)'	System	30 Apr 2021 07:03:36

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[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 (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-30T00:03:30-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '72eaae88-7218-4456-9dd0-0d20d933c692'	System	30 Apr 2021 07:03:36
User entered 'No (N)'	System	30 Apr 2021 07:03:36

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-04-30T00:03:34-07:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '72eaae88-7218-4456-9dd0-0d20d933c692'	System	30 Apr 2021 07:03:36
User entered '30 Apr 2021 00:03:34'	System	30 Apr 2021 07:03:36

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:32:03

US3682018

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:32:03
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:32:03

US3682018

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 23:02:48

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 18:42:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-28T13:31:37-08:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '39e5dfd4-f853-4060-a264-df419a75a841'	System	28 Feb 2021 21:31:43
User entered 'No (N)'	System	28 Feb 2021 21:31:43

US3682018

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 23:02:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:42:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3B7B9BB-E90E-473D-B2ED-38DFD563F23E)', Time: '2021-02-28T13:31:41-08:00', User OID: 'PatientReportedOutcome (US3682018)', ODM File OID: '39e5dfd4-f853-4060-a264-df419a75a841' User entered '28 Feb 2021 13:31:41'	System	28 Feb 2021 21:31:43
	System	28 Feb 2021 21:31:43

US3682018

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4)	18 Nov 2020 20:27:24

US3682018

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:09:15
User entered '18 Nov 2020'	Mitchell Stern (b) (4)	18 Nov 2020 20:27:24

US3682018

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:09:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4)	18 Nov 2020 20:27:24

US3682018

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:09:15
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	18 Nov 2020 20:27:24

US3682018

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4)	18 Nov 2020 20:27:29

US3682018

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:59:10
User entered 'I'	System	18 Nov 2020 20:27:29

US3682018

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	21 Dec 2020 22:48:35

US3682018

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '21 Dec 2020'	Mitchell Stern (b) (4)	21 Dec 2020 22:48:35

US3682018

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Contact Made (CONTACT MADE)'	Mitchell Stern (b) (4)	21 Dec 2020 22:48:35

US3682018

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	Mitchell Stern (b) (4)	21 Dec 2020 22:48:35

US3682018

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	21 Dec 2020 22:48:41

US3682018

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User entered 'I'	System	21 Dec 2020 22:48:41

US3682018

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	20 Jan 2021 23:59:22

US3682018

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '20 Jan 2021'	Mitchell Stern (b) (4)	20 Jan 2021 23:59:22

US3682018

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Contact Made (CONTACT MADE)'	Mitchell Stern (b) (4)	20 Jan 2021 23:59:22

US3682018

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	Mitchell Stern (b) (4)	20 Jan 2021 23:59:22

US3682018

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	20 Jan 2021 23:59:26

US3682018

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User entered 'I'	System	20 Jan 2021 23:59:26

US3682018

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	17 Feb 2021 19:04:56

US3682018

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '17 Feb 2021'	Mitchell Stern (b) (4)	17 Feb 2021 19:04:56

US3682018

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Contact Made (CONTACT MADE)'	Mitchell Stern (b) (4)	17 Feb 2021 19:04:56

US3682018

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 19:04:56

US3682018

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	17 Feb 2021 19:05:02

US3682018

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User entered '1'	System	17 Feb 2021 19:05:02

US3682018

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	Simone Riley (b) (4)	24 Mar 2021 21:47:17

US3682018

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '24 Mar 2021'	Simone Riley (b) (4)	24 Mar 2021 21:47:17

US3682018

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Clinic (Clinic)'	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:47:17

US3682018

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User entered 'VISIT4'	System	24 Mar 2021 21:47:17

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	Simone Riley (b) (4)	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '24 Mar 2021'	Simone Riley (b) (4)	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '13:22'	Simone Riley (b) (4)	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User entered '24 Mar 2021 13:22'	System	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '97.7' F	Simone Riley (b) (4)	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Oral (Oral)'	Simone Riley (b) (4)	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	Simone Riley (b) (4)	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '72'	Simone Riley (b) (4)	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User entered 'bpm'	System	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '12'	Simone Riley (b) (4)	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User entered 'breaths/min'	System	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '113'	Simone Riley (b) (4)	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User entered 'mmHg'	System	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '69'	Simone Riley (b) (4)	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User entered 'mmHg'	System	30 Mar 2021 16:52:20

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04

US3682018

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04

US3682018

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:47:25

US3682018

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '24 Mar 2021'	Simone Riley (b) (4)	24 Mar 2021 21:47:25

US3682018

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	Simone Riley (b) (4)	30 Mar 2021 16:52:42

US3682018

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '24 Mar 2021'	Simone Riley (b) (4)	30 Mar 2021 16:52:42

US3682018

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '13:38'	Simone Riley (b) (4)	30 Mar 2021 16:52:42

US3682018

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User entered '24 Mar 2021 13:38'	System	30 Mar 2021 16:52:42

US3682018

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	Simone Riley (b) (4)	24 Mar 2021 21:47:30

US3682018

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:57:04
User entered 'I'	System	24 Mar 2021 21:47:30

US3682018

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	21 Apr 2021 21:47:06
	(b) (4)	

US3682018

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '21 Apr 2021'	Mitchell Stern (b) (4)	21 Apr 2021 21:47:06
	(b) (4)	

US3682018

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	21 Apr 2021 21:47:06

US3682018

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:47:06
	(b) (4)	

US3682018

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	21 Apr 2021 21:47:12
	(b) (4)	

US3682018

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 21:47:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:02:48

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:03:12
User closed query 'This date is not in source document per source document.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 17:58:24
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
Query 'This date is not in source document per source document.' answered with 'Availability of progress notes documenting 05FEB2021 as date of telephone contact and subsequent illness visit confirmed.' (Site from CRA).	Jesse Clark (b) (4)	08 Mar 2021 17:55:28
User opened query 'This date is not in source document per source document.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:48:55
User closed query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:47:51
Query 'This is not in source document. Please verify and update accordingly.' answered with 'updated per source' (Site from CRA).	Mitchell Stern (b) (4)	22 Feb 2021 22:20:37
User entered '5 Feb 2021' reason for change: Data Entry Error	Mitchell Stern (b) (4)	22 Feb 2021 22:20:25
User opened query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 00:32:57
User entered '3 Feb 2021'	Jesse Clark (b) (4)	06 Feb 2021 00:46:50

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:02:48

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:03:12
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '11:57'	Jesse Clark (b) (4)	06 Feb 2021 00:46:50

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:02:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:33
User entered '5 Feb 2021 11:57'	System	22 Feb 2021 22:20:25
User entered '3 Feb 2021 11:57'	System	06 Feb 2021 00:46:50

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:02:48

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:03:12
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Safety Call (Safety Call)'	Jesse Clark (b) (4)	06 Feb 2021 00:46:50

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:02:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:03:12
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	Jesse Clark (b) (4)	06 Feb 2021 00:46:50

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 1 (Day 1)'	Jesse Clark (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:33:26
User entered '2 Feb 2021'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:33:28
User entered '0'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:33:30
User entered missing code ND - Not Done.	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User entered '%'	System	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:33:32
User entered missing code ND - Not Done.	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:33:36
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:33:46
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:33:49
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:33:53
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:33:56
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:33:59
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:34:02
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:34:04
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:34:06
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:34:08
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:34:10
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:34:12
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:34:14
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:34:17
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:34:19
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:34:22
User entered 'Mild (Mild)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:48:12

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 2 (Day 2)'	Jesse Clark (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:35:19
User entered '3 Feb 2021'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:35:21
User entered '0'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:35:50
User entered missing code ND - Not Done.	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User entered '%'	System	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:35:53
User entered '100.5' F	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:35:58
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:00
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:04
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:06
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:08
User entered 'Mild (Mild)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:12
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:14
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:16
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:18
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:23
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:28
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:39
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:43
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:44
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:46
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:36:49
User entered 'Mild (Mild)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:49:07

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 3 (Day 3)'	Jesse Clark (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:00
User entered '4 Feb 2021'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:02
User entered '0'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:03
User entered missing code ND - Not Done.	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User entered '%'	System	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:05
User entered missing code ND - Not Done.	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:15
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:17
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:18
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:20
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:22
User entered 'Mild (Mild)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:27
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:29
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:31
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:33
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:35
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:37
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:39
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:44
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:46
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:48
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:37:51
User entered 'Mild (Mild)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:50:02

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 4 (Day 4)'	Jesse Clark (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:01
User entered '5 Feb 2021'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:03
User entered '0'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:06
User entered '99'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User entered '%'	System	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:08
User entered '98.7' F	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:12
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:14
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:16
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:18
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:20
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:22
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:27
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:29
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:32
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:36
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:39
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:42
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:45
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:47
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:49
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:38:51
User entered 'Mild (Mild)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:51:14

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 5 (Day 5)'	Jesse Clark (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:07
User entered '6 Feb 2021'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:10
User entered '0'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:16
User entered '99'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User entered '%'	System	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:19
User entered '98.5' F	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:23
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:25
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:27
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:29
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:35
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:37
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:39
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:43
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:45
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:48
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:51
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:54
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:56
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:39:59
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:01
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:03
User entered 'Mild (Mild)'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:22:39

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 6 (Day 6)'	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:13
User entered '7 Feb 2021'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:17
User entered '0'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:19
User entered '98'	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User entered '%'	System	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:21
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Feb 2021 21:24:24
User entered '97.5' F reason for change: Data Entry Error	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:24:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Feb 2021 21:23:29
User entered '97' (non-conformant).	Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:25
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:27
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:32
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:38
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:41
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:44
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:51
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:52
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:54
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:56
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:40:58
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:41:01
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:41:03
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:41:08
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:41:10
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	(b) (4) Jesse Clark (b) (4) (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:41:12
User entered 'None (None)' reason for change: Data Entry Error	Jesse Clark (b) (4)	07 Feb 2021 21:24:24
User entered empty.	Jesse Clark (b) (4)	07 Feb 2021 21:23:29

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 7 (Day 7)'	(b) (4) Oladunni Adeyiga (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:41:49
User entered '8 Feb 2021'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:41:52
User entered '0'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:41:55
User entered '98'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User entered '%'	System	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:41:57
User entered '97.9' F	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:00
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:02
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:04
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:05
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:07
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:09
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:11
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:14
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:15
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:18
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:20
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:22
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:24
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:26
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:29
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:42:30
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	09 Feb 2021 01:09:16

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:43:13
User entered '05 Feb 2021'	(b) (4), (b) (6)	10 Feb 2021 00:52:01

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[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 17:30:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:43:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 00:52:01

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[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 17:30:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:51:39
User closed query 'Unable to locate the test result in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:51:35
Query 'Unable to locate the test result in source document. Please verify and update accordingly.' answered with 'Availability of source documentation confirmed.' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 21:37:22
User opened query 'Unable to locate the test result in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 01:02:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 01:02:26
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:57:48
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 00:52:01

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:03:01
User entered '05 Feb 2021'	(b) (4), (b) (6)	10 Feb 2021 00:52:01

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:03:03
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	10 Feb 2021 00:52:01

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:03:06
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 00:52:01

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[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 17:30:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:03:09
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 00:52:01

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:03:13
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 00:52:01

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:46
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:03:15
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 00:52:01

US3682018

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:30:46
User entered '0'	System	10 Feb 2021 00:52:01

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:02:48

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User closed query 'Per ETRTR: Please complete data entry in Severity Assessment page, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:08:16
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:08:14
Query 'Per ETRTR: Please complete data entry in Severity Assessment page, thanks.' answered with 'Severity Assessment completed' (Site from CRA).	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:45:43
User opened query 'Per ETRTR: Please complete data entry in Severity Assessment page, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 21:33:43
User entered '10 Dec 2020'	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:29

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:02:48

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:08:14
User entered '11:30'	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:29

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:02:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:03
User entered '10 Dec 2020 11:30'	System	11 Dec 2020 18:46:29

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:02:48

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:08:14
User entered 'Safety Call (Safety Call)'	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:29

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:02:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:08:14
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:29

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 1 (Day 1)'	(b) (4) Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '09 Dec 2020'	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '0'	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User closed query 'Per CDM:RQ: Response noted. Please review and update 'Temperature' as 'not done' for day 2.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 11:33:43
Query 'Per CDM:RQ: Response noted. Please review and update 'Temperature' as 'not done' for day 2.Thank you.' answered with 'Day 2 entry updated.' (Site from DM).	Jesse Clark (b) (4) (b) (4)	25 Jan 2021 18:47:59
User opened query 'Per CDM:RQ: Response noted. Please review and update 'Temperature' as 'not done' for day 2.Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:47:41
User closed query 'Per CDM:Requery:Response noted,however kindly consider to update "Not Done" for Temperature for day 1 and 2,if not collected.Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:47:41
Query 'Per CDM:Requery:Response noted,however kindly consider to update "Not Done" for Temperature for day 1 and 2,if not collected.Thank you.' answered with 'Noted' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 19:04:09
User opened query 'Per CDM:Requery:Response noted,however kindly consider to update "Not Done" for Temperature for day 1 and 2,if not collected.Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 05:21:55
User closed query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 1 and 2. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 05:17:44
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:34:30
Query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 1 and 2. If not collected, please consider recording as Not Done.' answered with 'updated as requested' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 23:06:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 23:06:47
User opened query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 1 and 2. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 23:28:18

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User entered '%'	System	20 Jan 2021 23:06:47
User entered empty.	System	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:41:31
DataPoint Un-verified.	(b) (4), (b) (6)	22 Jan 2021 19:04:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:04:02
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: New Information	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:52:26
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:46:49

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 2 (Day 2)'	(b) (4) Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '10 Dec 2020'	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '0'	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 23:07:20
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User entered '%'	System	20 Jan 2021 23:07:20
User entered empty.	System	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:24:59
DataPoint Un-verified.	Jesse Clark (b) (4)	25 Jan 2021 18:48:12
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Jesse Clark (b) (4)	25 Jan 2021 18:48:12
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered empty.	Susan Reed (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 20:46:00
User entered empty.	Susan Reed (b) (4) (b) (4)	11 Dec 2020 18:50:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '11 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	21 Jan 2021 20:34:30
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '99'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User entered '%'	System	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User closed query 'Per ETRTR: Please add temperature at Illness Visit Day 1, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 23:56:09
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:34:30
Query 'Per ETRTR: Please add temperature at Illness Visit Day 1, thanks.' answered with 'query resolved' (Site from CRA).	Mitchell Stern (b) (4) (b) (4)	23 Dec 2020 00:45:38
User entered '98.6' F reason for change: Per Query Resolution	Mitchell Stern (b) (4) (b) (4)	23 Dec 2020 00:45:33
User opened query 'Per ETRTR: Please add temperature at Illness Visit Day 1, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 21:32:50
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 20:47:26

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '12 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '98'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User entered '%'	System	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '101.1' F	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:26:22

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '13 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	21 Jan 2021 20:34:30
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '96'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User entered '%'	System	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '100.7' F	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 01:27:35

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 6 (Day 6)'	(b) (4) Oladunni Adeyiga (b) (4)	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '14 Dec 2020'	Oladunni Adeyiga (b) (4) (b) (4)	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '0'	Oladunni Adeyiga (b) (4) (b) (4)	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '98'	Oladunni Adeyiga (b) (4) (b) (4)	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User entered '%'	System	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 21 Jan 2021 20:34:30
User entered '99.6' F	Oladunni Adeyiga (b) (4)	15 Dec 2020 00:42:32
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4)	15 Dec 2020 00:42:32
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 21 Jan 2021 20:34:30
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	15 Dec 2020 00:42:32
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Moderate (Moderate)'	Oladunni Adeyiga (b) (4)	15 Dec 2020 00:42:32
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4) (b) (4)	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	15 Dec 2020 00:42:32
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4)	15 Dec 2020 00:42:32
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	15 Dec 2020 00:42:32
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Oladunni Adeyiga (b) (4) (b) (4)	15 Dec 2020 00:42:32

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	15 Dec 2020 00:42:32
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 7 (Day 7)'	(b) (4) Timothy Hall (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '15 Dec 2020'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '0'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '97'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User entered '%'	System	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '98.5' F	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Moderate (Moderate)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Timothy Hall (b) (4) (b) (4)	15 Dec 2020 23:32:28

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 8 (Day 8)'	(b) (4) Mitchell Stern (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '16 Dec 2020'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '0'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '93'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User entered '%'	System	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '99.3' F	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	17 Dec 2020 00:48:24

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 9 (Day 9)'	Jesse Clark (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '17 Dec 2020'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '0'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '99'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User entered '%'	System	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '98.3' F	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4)	17 Dec 2020 23:58:36
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	17 Dec 2020 23:58:36

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 10 (Day 10)'	Jesse Clark (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '18 Dec 2020'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '0'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '98'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User entered '%'	System	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '95.6' F	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4)	18 Dec 2020 23:57:41
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'Mild (Mild)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	18 Dec 2020 23:57:41

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 11 (Day 11)'	Jesse Clark (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '19 Dec 2020'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '0'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '98'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User entered '%'	System	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '98.2' F	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4)	21 Dec 2020 18:41:07
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4)	21 Dec 2020 18:41:07
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jesse Clark (b) (4)	21 Dec 2020 18:41:07
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4)	21 Dec 2020 18:41:07
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:41:07

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 12 (Day 12)'	Jesse Clark (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '20 Dec 2020'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '0'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '98'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User entered '%'	System	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '97.1' F	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Jesse Clark (b) (4) (b) (4)	21 Dec 2020 18:50:46

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User closed query 'Per CDM, per sponsor review: According to protocol, participants will be monitored by the study investigator for a 14-day period after diagnosis. Please review and, if applicable, add an additional line to record symptoms or mark as assessment not done. Else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 17:47:14
Query 'Per CDM, per sponsor review: According to protocol, participants will be monitored by the study investigator for a 14-day period after diagnosis. Please review and, if applicable, add an additional line to record symptoms or mark as assessment not done. Else clarify.' answered with 'participant was not followed beyond the 13 days. PD noted ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:00:19
User opened query 'Per CDM, per sponsor review: According to protocol, participants will be monitored by the study investigator for a 14-day period after diagnosis. Please review and, if applicable, add an additional line to record symptoms or mark as assessment not done. Else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:03:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Day 13 (Day 13)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '21 Dec 2020'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '0'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '95'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User entered '%'	System	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered '97.3' F	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4)	21 Dec 2020 23:04:05
	(b) (4)	

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:02:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:30
User entered 'None (None)'	Mitchell Stern (b) (4) (b) (4)	21 Dec 2020 23:04:05

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:40:03
User entered '11 Dec 2020'	Mitchell Stern (b) (4) (b) (4)	15 Dec 2020 00:55:56

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[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 17:31:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:40:03
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	15 Dec 2020 00:55:56

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[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 17:31:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:40:03
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)	16 Dec 2020 10:04:14
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 'Form completed' (Site from System).	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:01:09
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	15 Dec 2020 00:55:56
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	15 Dec 2020 00:55:56

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:40:03
User entered '11 Dec 2020'	Mitchell Stern (b) (4) (b) (4)	15 Dec 2020 00:55:56

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:40:03
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Mitchell Stern (b) (4) (b) (4)	15 Dec 2020 00:55:56

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:40:03
User entered empty.	Mitchell Stern (b) (4) (b) (4)	15 Dec 2020 00:55:56

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[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 17:31:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:40:03
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	15 Dec 2020 00:55:56

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:40:03
User entered empty.	Mitchell Stern (b) (4) (b) (4)	15 Dec 2020 00:55:56

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:40:03
User entered empty.	Mitchell Stern (b) (4) (b) (4)	15 Dec 2020 00:55:56

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:02:48

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:18
User entered 'I'	System	15 Dec 2020 00:55:56

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:02:48

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:02:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:02:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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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 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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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 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'Yes (Y)' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	21 Jan 2021 01:03:24
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:46:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User closed query 'This start date is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 00:34:34
Query 'This start date is not in source document. Please verify and update accordingly.' answered with 'Start date confirmed in source document (COVID-19 Symptom Log for 16DEC2020). ' (Site from CRA).	Jesse Clark (b) (4)	22 Feb 2021 21:43:13
User opened query 'This start date is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 00:28:25
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 00:27:25
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:14:08
User closed query 'As answer is Yes on 8 Jan 21. please complete this section.' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 23:54:31
Query 'As answer is Yes on 8 Jan 21. please complete this section.' answered with 'data update complete' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 17:58:51
User entered '16 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 17:58:35
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:38:13
User opened query 'As answer is Yes on 8 Jan 21. please complete this section.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 20:37:54
User entered empty.	Sandy MacNicoll (b) (4)	23 Dec 2020 19:44:58

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:46:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 00:27:48
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:13:47
User entered '16 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 17:58:35
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 20:38:19
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4)	23 Dec 2020 19:44:58

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:13:42
User entered '93' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 17:58:35
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 20:38:21
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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Folder: Covid-19 Assessment 10 Dec 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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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 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:02:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:02:48

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:02:48

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:02:48

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:02:48

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:02:48

[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 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:02:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

US3682018

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:02:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:38:13
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	23 Dec 2020 19:44:58

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 23:02:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:24:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:24:34
User entered '13 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 23:02:48

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:24:34
User closed query 'Per CDM: Thank you for the response. Please update the field when data is available.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 08:29:32
Query 'Per CDM: Thank you for the response. Please update the field when data is available.' answered with 'Updated data' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 00:25:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 01:26:24
User opened query 'Per CDM: Thank you for the response. Please update the field when data is available.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 04:10:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 04:06:17
Query 'Data is required. Please complete.' answered with 'collection date is for today. In process' (Site from System).	Mitchell Stern (b) (4)	15 Dec 2020 23:12:06
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 21:28:59
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:24:34
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 01:26:13
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 23:02:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:24:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 01:26:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 04:06:27
Query 'Data is required. Please complete.' answered with 'collection date is for the future.' (Site from System).	Mitchell Stern (b) (4)	15 Dec 2020 23:12:21
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 21:28:59
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:24:34
User entered '17 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 01:26:13
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 23:02:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:24:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 00:56:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 04:06:35
Query 'Data is required. Please complete.' answered with 'collection date is for the future.' (Site from System).	Mitchell Stern (b) (4)	15 Dec 2020 23:12:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 21:28:59
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:24:34
User entered '19 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 00:56:37
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 23:02:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:24:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 00:32:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 04:06:42
Query 'Data is required. Please complete.' answered with 'collection date is for the future.' (Site from System).	Mitchell Stern (b) (4)	15 Dec 2020 23:12:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 21:28:59
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:24:34
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 00:32:59
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 23:02:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:24:34
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	05 Jan 2021 00:46:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 04:06:51
Query 'Data is required. Please complete.' answered with 'collection date is for the future.' (Site from System).	Mitchell Stern (b) (4)	15 Dec 2020 23:12:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 21:28:59
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:24:34
User entered '31 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	05 Jan 2021 00:46:52
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 23:02:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:24:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 21:57:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 04:06:58
Query 'Data is required. Please complete.' answered with 'collection date is for the future.' (Site from System).	Mitchell Stern (b) (4)	15 Dec 2020 23:13:04
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 21:28:59
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:24:34
Query 'Per GCL Lab Recon: Saliva: Sample dated 08JAN2021 for Day 28 is recorded in EDC, however sample is reported with 08JAN2020 for Day 28 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:45:49
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 08JAN2021 for Day 28 is recorded in EDC, however sample is reported with 08JAN2020 for Day 28 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 12:28:21
User entered '08 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 21:57:21
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 21:28:59

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 23:02:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:14:48
User entered '07 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 23:02:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:54
User entered '09 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 23:02:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:22:25
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:22:28
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 23:02:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:22:08
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:22:10
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 23:02:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:37
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:38
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 23:02:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:46
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:48
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 23:02:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 23:02:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:53
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:05
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:21:56
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 22:21:30

US3682018

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:11:58
User entered 'Yes (Y)'	Schuyler Thomas (b) (4) (b) (4)	11 Dec 2020 21:32:57

US3682018

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:11:58
User entered '11 Dec 2020'	Schuyler Thomas (b) (4) (b) (4)	11 Dec 2020 21:32:57

US3682018

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:11:58
User entered 'Clinic (Clinic)'	Schuyler Thomas (b) (4) (b) (4)	11 Dec 2020 21:32:57

US3682018

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	11 Dec 2020 21:32:57

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:19:27
User entered 'Yes (Y)'	Schuyler Thomas (b) (4) (b) (4)	11 Dec 2020 21:39:54

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:19:27
User entered '11 Dec 2020'	Schuyler Thomas (b) (4) (b) (4)	11 Dec 2020 21:39:54

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:19:27
User entered '12:15'	Schuyler Thomas (b) (4) (b) (4)	11 Dec 2020 21:39:54

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User entered '11 Dec 2020 12:15'	System	11 Dec 2020 21:39:54

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:19:27
User entered '70' in	Schuyler Thomas (b) (4)	11 Dec 2020 21:39:54
DataPoint set to visible.	(b) (4) System	11 Dec 2020 21:32:57

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:19:27
User entered '180' lb	Schuyler Thomas (b) (4)	11 Dec 2020 21:39:54
DataPoint set to visible.	(b) (4)	
	System	11 Dec 2020 21:32:57

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:19:27
User entered '98.6' F	Schuyler Thomas (b) (4)	11 Dec 2020 21:39:54
	(b) (4)	

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:19:27
User entered 'Oral (Oral)'	Schuyler Thomas (b) (4) (b) (4)	11 Dec 2020 21:39:54

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:19:27
User entered empty.	Schuyler Thomas (b) (4) (b) (4)	11 Dec 2020 21:39:54

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:19:27
User entered '94'	Schuyler Thomas (b) (4)	11 Dec 2020 21:39:54
	(b) (4)	

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Dec 2020 21:39:54

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:19:27
User entered '16'	Schuyler Thomas (b) (4)	11 Dec 2020 21:39:54
	(b) (4)	

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Dec 2020 21:39:54

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:19:27
User entered '111'	Schuyler Thomas (b) (4) (b) (4)	11 Dec 2020 21:39:54

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Dec 2020 21:39:54

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:19:27
User entered '75'	Schuyler Thomas (b) (4)	11 Dec 2020 21:39:54
	(b) (4)	

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Dec 2020 21:39:54

US3682018

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:19:37
User entered 'Yes (Y)'	Schuyler Thomas (b) (4) (b) (4)	11 Dec 2020 21:40:15

US3682018

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:19:37
User entered '11 Dec 2020'	Schuyler Thomas (b) (4) (b) (4)	11 Dec 2020 21:40:15

US3682018

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 23:02:48

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:20:47
User entered 'Yes (Y)'	Schuyler Thomas (b) (4) (b) (4)	11 Dec 2020 21:41:03

US3682018

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:20:47
User entered '11 Dec 2020'	Schuyler Thomas (b) (4) (b) (4)	11 Dec 2020 21:41:03

US3682018

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:04:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Feb 2021 00:00:32

US3682018

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:04:54
User entered '05 Feb 2021'	(b) (4), (b) (6)	06 Feb 2021 00:00:32

US3682018

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:04:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Feb 2021 00:00:32

US3682018

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:26
User entered 'SICKD1'	System	06 Feb 2021 00:00:32

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:17:59
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:18:01
User entered '5 Feb 2021'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:18:04
User entered '15:55'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User entered '5 Feb 2021 15:55'	System	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:18:08
User entered '74' in	Jesse Clark (b) (4)	06 Feb 2021 00:39:31
DataPoint set to visible.	(b) (4) System	06 Feb 2021 00:00:32

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:18:11
User entered '90.6' kg	Jesse Clark (b) (4)	06 Feb 2021 00:39:31
DataPoint set to visible.	(b) (4) System	06 Feb 2021 00:00:32

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:18:15
User entered '98.7' F	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:18:17
User entered 'Oral (Oral)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:18:22
User entered empty.	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:18:25
User entered '80'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User entered 'bpm'	System	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:18:29
User entered '16'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User entered 'breaths/min'	System	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:18:33
User entered '110'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User entered 'mmHg'	System	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:18:35
User entered '71'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34
User entered 'mmHg'	System	06 Feb 2021 00:39:31

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 09:16:34

US3682018

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:34

US3682018

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:18:45
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:39:44

US3682018

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 01:18:45
User entered '5 Feb 2021'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:39:44

US3682018

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 23:02:48

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:57:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Feb 2021 00:00:52

US3682018

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:16:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:57:29
User entered '05 Feb 2021'	(b) (4), (b) (6)	06 Feb 2021 00:00:52

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 21:55:48

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:01
User entered '08 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 21:55:48

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:01
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Jan 2021 21:55:48

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User entered 'SICKD28'	System	08 Jan 2021 21:55:48

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:18
User entered 'Yes (Y)'	Schuyler Thomas (b) (4) (b) (4)	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:18
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	08 Jan 2021 22:16:38
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	08 Jan 2021 22:16:38
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	08 Jan 2021 22:16:38
User entered '08 Jan 2021' reason for change: New Information	Schuyler Thomas (b) (4) (b) (4)	08 Jan 2021 22:16:38
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	08 Jan 2021 22:16:21
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	08 Jan 2021 22:16:21
User entered '08 Jan 2020'	Schuyler Thomas (b) (4) (b) (4)	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:18
User entered '13:35'	Schuyler Thomas (b) (4) (b) (4)	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User entered '08 Jan 2021 13:35'	System	08 Jan 2021 22:16:38
User entered '08 Jan 2020 13:35'	System	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:18
User entered '98.1' F	Schuyler Thomas (b) (4) (b) (4)	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:18
User entered 'Oral (Oral)'	Schuyler Thomas (b) (4) (b) (4)	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:18
User entered empty.	Schuyler Thomas (b) (4) (b) (4)	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:18
User entered '78'	Schuyler Thomas (b) (4) (b) (4)	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User entered 'bpm'	System	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:18
User entered '16'	Schuyler Thomas (b) (4) (b) (4)	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User entered 'breaths/min'	System	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:18
User entered '112'	Schuyler Thomas (b) (4) (b) (4)	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User entered 'mmHg'	System	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:18
User entered '72'	Schuyler Thomas (b) (4) (b) (4)	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User entered 'mmHg'	System	08 Jan 2021 22:16:21

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:28
User entered 'Yes (Y)'	Schuyler Thomas (b) (4) (b) (4)	08 Jan 2021 22:16:49

US3682018

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:28
User entered '08 Jan 2021'	Schuyler Thomas (b) (4) (b) (4)	08 Jan 2021 22:16:49

US3682018

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 23:02:48

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 21:56:02

US3682018

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 23:02:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:39
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:49
User entered '08 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 21:56:02

US3682018

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

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:00:44
User entered 'Yes (Y)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:48:08

US3682018

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

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:00:44
User entered '27 Jan 2021'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:48:08

US3682018

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

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:00:44
User entered 'Clinic (Clinic)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:48:08

US3682018

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

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 22:48:08

US3682018

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:48

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:01:34
User entered '8 Jan 2021' reason for change: Data Entry Error	Simone Riley (b) (4)	03 Feb 2021 21:37:44
User entered '6 Jan 2021'	(b) (4) Christopher Blades (b) (4)	27 Jan 2021 22:49:19

US3682018

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:41:43

US3682018

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:01:34
User entered 'Yes (Y)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:49:19

US3682018

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:41:43

US3682018

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:01:34
User entered '27 Jan 2021'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:49:19

US3682018

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:01:34
User entered 'Placebo (Placebo)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:49:19

US3682018

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:01:34
User entered 'Placebo (Placebo)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:49:19

US3682018

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:01:34
User entered 'Placebo (Placebo)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:49:19

US3682018

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:01:34
User entered 'Yes (Y)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:49:19

US3682018

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered '1'	System	27 Jan 2021 22:49:19

US3682018

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'I'	System	27 Jan 2021 22:49:19

US3682018

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:01:47
User entered missing code ND - Not Done.	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:01:48
User entered missing code ND - Not Done.	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered empty.	System	27 Jan 2021 22:50:42
DataPoint set to visible.	System	27 Jan 2021 22:49:19

US3682018

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:01:47
User entered missing code ND - Not Done.	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:01:48
User entered missing code ND - Not Done.	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered empty.	System	27 Jan 2021 22:50:42
DataPoint set to visible.	System	27 Jan 2021 22:49:19

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User accepted default value 'Pre-Dose (PREDOSE)'	Christopher Blades (b) (4)	27 Jan 2021 22:50:42
	(b) (4)	

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:02:47
User entered 'Yes (Y)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:02:55
User entered '27 Jan 2021'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:02:58
User entered '13:54'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered '27 Jan 2021 13:54'	System	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:13
User entered '98.0' F	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:18
User entered 'Oral (Oral)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:20
User entered empty.	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:25
User entered '72'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'bpm'	System	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:31
User entered '18'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'breaths/min'	System	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:35
User entered '114'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'mmHg'	System	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:37
User entered '76'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'mmHg'	System	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:01:47
User entered missing code ND - Not Done.	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:01:48
User entered missing code ND - Not Done.	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered empty.	System	27 Jan 2021 22:50:42
DataPoint set to visible.	System	27 Jan 2021 22:49:19

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User accepted default value 'Post-Dose (POSTDOSE)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:46
User entered 'Yes (Y)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:49
User entered '27 Jan 2021'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:51
User entered '14:39'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered '27 Jan 2021 14:39'	System	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:54
User entered '98.7' F	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:55
User entered 'Oral (Oral)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:58
User entered empty.	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:04:01
User entered '65'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'bpm'	System	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:04:03
User entered '18'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'breaths/min'	System	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:04:06
User entered '144'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'mmHg'	System	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:04:08
User entered '78'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:42

US3682018

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'mmHg'	System	27 Jan 2021 22:50:42

US3682018

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

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:05:01
User entered 'Yes (Y)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:49

US3682018

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

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:05:03
User entered '27 Jan 2021'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:50:49

US3682018

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	27 Jan 2021 22:51:08

US3682018

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Christopher Blades (b) (4)	27 Jan 2021 22:51:08

US3682018

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Christopher Blades (b) (4)	27 Jan 2021 22:51:08

US3682018

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'mRNA-1273'	System	27 Jan 2021 22:51:08
DataPoint set to visible.	System	27 Jan 2021 22:49:19

US3682018

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User closed query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:03:29
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 23:03:27
Query 'This is not in source document. Please verify and update accordingly.' answered with 'Source documentation confirmed.' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 21:45:50
User opened query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 20:12:39
User entered '27 Jan 2021'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:51:08

US3682018

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:03:33
User entered '14:07'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:51:08

US3682018

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered '27 Jan 2021 14:07'	System	27 Jan 2021 22:51:08

US3682018

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:03:37
User entered 'Left Arm (LEFT ARM)'	Christopher Blades (b) (4) (b) (4)	27 Jan 2021 22:51:08

US3682018

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 23:03:38
User entered 'ONCE'	System	27 Jan 2021 22:51:08

US3682018

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'INTRAMUSCULAR'	System	27 Jan 2021 22:51:08

US3682018

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:13:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 01:45:22

US3682018

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:13:59
User entered '27 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 01:45:22

US3682018

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:13:59
User entered '13:51'	(b) (4), (b) (6)	28 Jan 2021 01:45:22

US3682018

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered '27 Jan 2021 13:51'	System	28 Jan 2021 01:45:22

US3682018

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 01:45:33

US3682018

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:02:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:04:32
User closed query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 23:04:30
Query 'This is not in source document. Please verify and update accordingly.' answered with 'Source documentation confirmed.' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 21:44:41
User opened query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 20:17:12
User entered '27 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 01:45:33

US3682018

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:02:48

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:04:32
User entered '13:53'	(b) (4), (b) (6)	28 Jan 2021 01:45:33

US3682018

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered '27 Jan 2021 13:53'	System	28 Jan 2021 01:45:33

US3682018

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

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:18:18
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:10:03

US3682018

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

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered '1'	System	03 Feb 2021 23:10:03

US3682018

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:01
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:09:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:04:56
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:10:13

US3682018

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:01
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:09:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:04:56
User entered '3 Feb 2021'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:10:13

US3682018

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:01
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:09:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:04:56
User entered 'Contact Made (CONTACT MADE)'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:10:13

US3682018

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:01
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:09:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:04:56
User entered empty.	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:10:13

US3682018

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:01
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:09:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:05:01
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:10:18

US3682018

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:01
User entered 'I'	System	03 Feb 2021 23:10:18

US3682018

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:01
User entered '1'	System	03 Feb 2021 23:10:18
DataPoint set to visible.	System	03 Feb 2021 23:10:18

US3682018

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:05:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:29:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 09:52:16
Query 'Data is required. Please complete.' answered with 'data entry error; subject has not been seen for this visit ' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 16:06:19
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 16:05:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:05:39
User entered 'Yes (Y)'	Schuyler Thomas (b) (4)	06 Feb 2021 01:31:35

US3682018

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:05:22
User entered '23 Feb 2021' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:29:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:05:39
User entered '05 Feb 2021'	Schuyler Thomas (b) (4)	06 Feb 2021 01:31:35

US3682018

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:05:22
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Simone Riley (b) (4) (b) (4)	23 Feb 2021 22:29:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:05:39
User entered 'Clinic (Clinic)'	Schuyler Thomas (b) (4) (b) (4)	06 Feb 2021 01:31:35

US3682018

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'OLD29'	System	23 Feb 2021 22:29:04
User entered empty.	System	08 Feb 2021 16:05:39
User entered 'OLD29'	System	06 Feb 2021 01:31:35

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User accepted default value 'Pre-Dose (PREDOSE)'	Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36
	(b) (4)	

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:05:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 09:52:48
Query 'Data is required. Please complete.' answered with 'data entry error. visit has not occurred' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 16:05:15
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 16:04:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:04:51
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 16:03:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 16:03:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:03:25
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Feb 2021 01:32:36
User entered empty.	Schuyler Thomas (b) (4) (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:05:35
User entered '23 Feb 2021' reason for change: Data Entry Error	Simone Riley (b) (4) (b) (4)	23 Feb 2021 22:30:10
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	08 Feb 2021 16:04:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:04:51
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	08 Feb 2021 16:03:25
User entered '27 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:03:25
User entered empty.	Schuyler Thomas (b) (4) (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:05:47
User entered '13:37' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty; reason for change Data Entry Error	(b) (4)	08 Feb 2021 16:04:51
User entered '13:54' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:03:25
User entered empty.	Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered '23 Feb 2021 13:37'	System	23 Feb 2021 22:30:10
User entered empty.	System	08 Feb 2021 16:04:51
User entered '27 Jan 2021 13:54'	System	08 Feb 2021 16:03:25
User entered empty.	System	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:05:52
User entered '98.7' F reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty; reason for change Data Entry Error	(b) (4)	08 Feb 2021 16:04:51
User entered '98.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:03:25
User entered empty.	Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:05:55
User entered 'Oral (Oral)' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:04:51
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 16:03:25
	Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36
	(b) (4)	

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:05:58
User entered empty.	Schuyler Thomas (b) (4) (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:04
User entered '87' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty; reason for change Data Entry Error	(b) (4)	08 Feb 2021 16:04:51
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:03:25
User entered empty.	Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'bpm'	System	23 Feb 2021 22:30:10
User entered empty.	System	08 Feb 2021 16:04:51
User entered 'bpm'	System	08 Feb 2021 16:03:25
User entered empty.	System	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:07
User entered '12' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:04:51
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 16:03:25
	Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36
	(b) (4)	

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'breaths/min'	System	23 Feb 2021 22:30:10
User entered empty.	System	08 Feb 2021 16:04:51
User entered 'breaths/min'	System	08 Feb 2021 16:03:25
User entered empty.	System	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:12
User entered '114' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty; reason for change Data Entry Error	(b) (4)	08 Feb 2021 16:04:51
User entered '114' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:03:25
User entered empty.	Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'mmHg'	System	23 Feb 2021 22:30:10
User entered empty.	System	08 Feb 2021 16:04:51
User entered 'mmHg'	System	08 Feb 2021 16:03:25
User entered empty.	System	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:14
User entered '66' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 16:04:51
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 16:03:25
	Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36
	(b) (4)	

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'mmHg'	System	23 Feb 2021 22:30:10
User entered empty.	System	08 Feb 2021 16:04:51
User entered 'mmHg'	System	08 Feb 2021 16:03:25
User entered empty.	System	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User accepted default value 'Post-Dose (POSTDOSE)'	Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 09:52:57
Query 'Data is required. Please complete.' answered with 'subject has not been seen for this visit' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 16:06:36
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Feb 2021 01:32:36
User entered empty.	Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:22
User entered '23 Feb 2021' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty.	(b) (4) Schuyler Thomas (b) (4) (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:27
User entered '14:22' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty.	(b) (4) Schuyler Thomas (b) (4) (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered '23 Feb 2021 14:22'	System	23 Feb 2021 22:30:10
User entered empty.	System	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:35
User entered '97.7' F reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty.	(b) (4) Schuyler Thomas (b) (4) (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:38
User entered 'Oral (Oral)' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty.	(b) (4) Schuyler Thomas (b) (4) (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:41
User entered empty.	Schuyler Thomas (b) (4) (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:46
User entered '71' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'bpm'	System	23 Feb 2021 22:30:10
User entered empty.	System	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:49
User entered '16' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'breaths/min'	System	23 Feb 2021 22:30:10
User entered empty.	System	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:53
User entered '108' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'mmHg'	System	23 Feb 2021 22:30:10
User entered empty.	System	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:06:54
User entered '71' reason for change: Data Entry Error	Simone Riley (b) (4)	23 Feb 2021 22:30:10
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'mmHg'	System	23 Feb 2021 22:30:10
User entered empty.	System	06 Feb 2021 01:32:36

US3682018

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:07:17
User entered 'Yes (Y)'	Simone Riley (b) (4) (b) (4)	23 Feb 2021 22:30:20

US3682018

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:07:17
User entered '23 Feb 2021'	Simone Riley (b) (4) (b) (4)	23 Feb 2021 22:30:20

US3682018

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:07:31
User entered 'Yes (Y)'	Simone Riley (b) (4) (b) (4)	23 Feb 2021 22:30:38

US3682018

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:07:39
User entered empty.	Simone Riley (b) (4) (b) (4)	23 Feb 2021 22:30:38

US3682018

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:07:41
User entered empty.	Simone Riley (b) (4) (b) (4)	23 Feb 2021 22:30:38

US3682018

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'mRNA-1273'	System	23 Feb 2021 22:30:38
DataPoint set to visible.	System	03 Feb 2021 23:10:18

US3682018

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:07:43
User entered '23 Feb 2021'	Simone Riley (b) (4) (b) (4)	23 Feb 2021 22:30:38

US3682018

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:07:45
User entered '13:52'	Simone Riley (b) (4) (b) (4)	23 Feb 2021 22:30:38

US3682018

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered '23 Feb 2021 13:52'	System	23 Feb 2021 22:30:38

US3682018

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:07:49
User entered 'Left Arm (LEFT ARM)'	Simone Riley (b) (4) (b) (4)	23 Feb 2021 22:30:38

US3682018

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 23:07:53
User entered 'ONCE'	System	23 Feb 2021 22:30:38

US3682018

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'INTRAMUSCULAR'	System	23 Feb 2021 22:30:38

US3682018

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:08:00
User entered 'Yes (Y)'	Simone Riley (b) (4) (b) (4)	23 Feb 2021 22:30:43

US3682018

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:51
User entered 'I'	System	23 Feb 2021 22:30:43

US3682018

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:41
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:08:15
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	02 Mar 2021 18:09:43

US3682018

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:41
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:08:15
User entered '2 Mar 2021'	Mitchell Stern (b) (4) (b) (4)	02 Mar 2021 18:09:43

US3682018

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:41
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:08:15
User entered 'Contact Made (CONTACT MADE)'	Mitchell Stern (b) (4) (b) (4)	02 Mar 2021 18:09:43

US3682018

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:41
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:08:15
User entered empty.	Mitchell Stern (b) (4) (b) (4)	02 Mar 2021 18:09:43

US3682018

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:41
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:08:30
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	02 Mar 2021 18:09:47

US3682018

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:41
User entered 'I'	System	02 Mar 2021 18:09:47

US3682018

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:46:27

US3682018

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered '24 Mar 2021'	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:46:27

US3682018

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[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 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered 'Clinic (Clinic)'	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:46:27

US3682018

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User entered 'OLD57'	System	24 Mar 2021 21:46:27

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered '24 Mar 2021'	Simone Riley (b) (4)	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered '13:22'	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User entered '24 Mar 2021 13:22'	System	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered '97.7' F	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered 'Oral (Oral)'	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered empty.	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered '72'	Simone Riley (b) (4)	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User entered 'bpm'	System	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered '12'	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User entered 'breaths/min'	System	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered '113'	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User entered 'mmHg'	System	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered '69'	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User entered 'mmHg'	System	24 Mar 2021 21:46:51

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33

US3682018

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33

US3682018

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	24 Mar 2021 21:47:01

US3682018

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered '24 Mar 2021'	Simone Riley (b) (4)	24 Mar 2021 21:47:01

US3682018

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:55:46

US3682018

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:55:46

US3682018

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:28:31
User entered '13:38'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:55:46

US3682018

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:33
User entered '24 Mar 2021 13:38'	System	24 Mar 2021 23:55:46

US3682018

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 23:02:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:53:47
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:45
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:56:42

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:25:43
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:11:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:11:21
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 22:59:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 22:59:48
Data point term sent to Coder	System	16 Sep 2020 22:58:56
User entered 'Nausea'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:25:54
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:26:01
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:26:04
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:26:59
User entered '14 Sep 2020'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:01
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User entered empty.	System	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:15
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:19
User entered '15 Sep 2020'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:20
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User entered empty.	System	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:26
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:29
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:33
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:36
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:38
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:41
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:43
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:45
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:47
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:49
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:27:51
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:28:00
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:29:34
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:29:46
User entered 'None (NONE)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:29:49
User entered 'l'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:29:52
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:29:54
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:29:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:30:07
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:30:08
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User entered '0'	System	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58
User entered '0'	System	16 Sep 2020 22:58:07

US3682018

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:58

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:34:22
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 23:24:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 23:24:44
Data point term sent to Coder	System	16 Sep 2020 23:24:29
User entered 'Vomiting'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:13:20
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:13:23
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:13:25
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:04
User entered '14 Sep 2020'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:05
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User entered empty.	System	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:07
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:15
User entered '15 Sep 2020'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:19
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User entered empty.	System	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:24
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:26
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:28
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:30
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:32
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:33
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:38
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:42
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:49
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:50
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:53
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:55
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:57
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:14:58
User entered 'None (NONE)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:15:03
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 21:11:38
User entered 'I'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:12:14
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:12:17
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:12:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:12:22
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:12:25
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User entered '0'	System	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04
User entered '0'	System	16 Sep 2020 23:23:38

US3682018

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:04

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:12:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 23:25:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 23:25:45
Data point term sent to Coder	System	16 Sep 2020 23:25:29
User entered 'Sore throat'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:12:50
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:12:54
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:12:57
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:13:09
User entered '14 Sep 2020'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:13:13
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User entered empty.	System	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:13:26
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:13:30
User entered '15 Sep 2020'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:13:32
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User entered empty.	System	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:13:42
User entered 'Grade 1/Mild (Grade 1/Mild)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:13:54
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 21:13:52
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 21:13:45
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:13:57
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:14:00
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:14:08
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:15:14
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:19:55
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:19:58
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:20:00
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:20:04
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:20:06
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:20:10
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:20:36
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:21:01
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:21:09
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 23:25:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 23:25:22
User entered 'None (NONE)' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:22
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 23:25:14
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:21:11
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Oct 2020 20:01:55
User entered '1' reason for change: Data Entry Error	Susan Reed (b) (4)	16 Oct 2020 20:01:55
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	16 Oct 2020 20:01:46
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:21:34
User entered '0'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:21:37
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. '(Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:58:46
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'form corrected' (Site from DM).	Susan Reed (b) (4) (b) (4)	16 Oct 2020 20:02:03
User entered '0' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	16 Oct 2020 20:01:46
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. '(Site from DM).	(b) (4), (b) (6)	15 Oct 2020 12:05:33
User entered '1'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:31:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:31:17
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:34:43
User entered empty.	Susan Reed (b) (4) (b) (4)	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User entered '0'	System	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16
User entered '0'	System	16 Sep 2020 23:25:14

US3682018

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:16

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:35:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:02:51
User entered 'USA-US081-2020-mRNA-1273-P301000004'	System	15 Dec 2020 14:02:47
User entered 'New'	(b) (4), (b) (6)	15 Dec 2020 14:02:47

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:37:56
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)	15 Dec 2020 01:02:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 01:02:44
Data point term sent to Coder	System	15 Dec 2020 01:01:19
User entered 'Covid 19'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:38:01
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:38:10
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:38:31
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:38:39
User closed query 'PV Query: COVID-19 symptoms have been reported starting on 09 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 00:15:02
Query 'PV Query: COVID-19 symptoms have been reported starting on 09 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' answered with 'updated' (Site from Safety).	Mitchell Stern (b) (4) (b) (4)	23 Dec 2020 00:25:26
User entered '9 Dec 2020' reason for change: Per Query Resolution	Mitchell Stern (b) (4) (b) (4)	23 Dec 2020 00:25:15
User opened query 'PV Query: COVID-19 symptoms have been reported starting on 09 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 15:08:34
User entered '11 Dec 2020'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:38:42
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:38:49
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Dec 2020 23:55:18
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	23 Dec 2020 23:55:18
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Dec 2020 23:55:00
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:15:25
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 00:14:34
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'query resolved' (Site from Safety).	Mitchell Stern (b) (4) (b) (4)	23 Dec 2020 23:55:49
User entered '19 Dec 2020' reason for change: Per Query Resolution	Mitchell Stern (b) (4) (b) (4)	23 Dec 2020 23:55:00
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 15:07:19
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:38:59
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:39:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:39:06
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:39:11
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:39:13
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:39:15
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:39:18
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:39:20
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:39:22
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:39:26
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:39:28
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:40:20
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:40:22
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:40:26
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 01:00:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 01:00:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:34
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 01:00:19
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:42:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 01:00:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 01:00:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:34
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 01:00:19
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 21:42:59
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 00:14:53
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' answered with 'query resolved' (Site from Safety).	Mitchell Stern (b) (4)	23 Dec 2020 23:55:55
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	23 Dec 2020 23:55:00
	(b) (4)	
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 15:08:17
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 01:00:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 01:00:34
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Susan Reed (b) (4)	15 Dec 2020 01:00:34
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 01:00:19
User entered empty.	Susan Reed (b) (4)	15 Dec 2020 01:00:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:43:01
User entered 'I'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:43:15
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:43:17
User entered '0'	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 21:43:53
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 00:14:42
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'query resolved' (Site from Safety).	Mitchell Stern (b) (4)	23 Dec 2020 23:55:59
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mitchell Stern (b) (4)	23 Dec 2020 23:55:00
New Information	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 15:07:37
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Susan Reed (b) (4)	15 Dec 2020 01:00:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:44:38
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:44:45
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 00:14:47
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 'query resolved' (Site from Safety).	Mitchell Stern (b) (4) (b) (4)	23 Dec 2020 23:56:04
User entered 'Pt denied medical intervention, as well as home treatments and medications.' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	23 Dec 2020 23:55:00
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)	21 Dec 2020 15:07:53
User entered empty.	Susan Reed (b) (4) (b) (4)	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:02:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Dec 2020 01:00:19

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:47:09
User coded data point as SOC: Infections and infestations, HLG: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pharyngitis streptococcal, LLT: Streptococcal pharyngitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Feb 2021 00:55:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Feb 2021 00:55:52
Data point term sent to Coder	System	06 Feb 2021 00:54:31
Coding entries removed.	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:53:31
User entered 'STREP THROAT' reason for change: New Information	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:53:31
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 23:12:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 23:12:31
Data point term sent to Coder	System	03 Feb 2021 23:11:51
User entered 'Sore throat'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:49:52
User entered 'Yes (Y)' reason for change: New Information	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:53:31
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:49:53
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:50:55
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:50:59
User entered '2 Feb 2021'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:51:08
User entered empty.	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User entered empty.	System	03 Feb 2021 23:11:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:51:02
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	17 Feb 2021 19:08:49
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:51:10
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	17 Feb 2021 19:09:01
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	17 Feb 2021 19:09:01
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	17 Feb 2021 19:08:49
User entered '7 Feb 2021' reason for change: New Information	Mitchell Stern (b) (4)	17 Feb 2021 19:08:49
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:51:11
User entered empty.	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User entered empty.	System	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:54:34
Query 'This is a grade 1 in source document. Please verify and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 21:54:32
User opened query 'This is a grade 1 in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 21:53:23
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 21:52:47
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 21:52:43
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: New Information	Jesse Clark (b) (4)	06 Feb 2021 00:53:31
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mitchell Stern (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:53:26
User entered 'No (N)'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:53:28
User entered '0'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:53:31
User entered '0'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:53:33
User entered '0'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:53:35
User entered empty.	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:53:38
User entered empty.	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:53:41
User entered empty.	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:53:43
User entered empty.	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:53:44
User entered '0'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:53:46
User entered '0'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:53:50
User entered '0'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:53:53
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:53:56
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:54:00
User entered 'None (NONE)' reason for change: New Information	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:53:31
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:54:03
User entered '0' reason for change: New Information	Jesse Clark (b) (4)	06 Feb 2021 00:53:31
User entered '1'	Mitchell Stern (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:54:06
User entered '1' reason for change: New Information	Jesse Clark (b) (4)	06 Feb 2021 00:53:31
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:54:19
User entered '0'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:54:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	17 Feb 2021 19:09:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:54:49
User entered empty.	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:10:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:59:01
User entered 'Participant reports onset of sore throat on evening of 2/2/2021, followed by fatigue and fever with Tmax 100.5F on 2/3/2021. Seen by Urgent Care on 2/3/2021, rapid strep test positive, treated with Azithromycin. Illness visit completed on 2/5/2021.' reason for change: New Information	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:53:31
User entered 'The pt denied other COVID symptoms.' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:46
User entered empty.	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User entered '0'	System	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27
User entered '1'	System	06 Feb 2021 00:53:31
User entered '0'	System	03 Feb 2021 23:11:29

US3682018

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:27

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Painful R arm - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Apr 2021 16:40:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 16:40:45
Data point term sent to Coder	System	01 Apr 2021 16:40:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Painful R arm - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 16:39:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 16:39:28
Query 'DM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms.	Coder Import (b) (4)	01 Apr 2021 16:39:27
' canceled (Site from System).		
Data point term sent to Coder	System	01 Apr 2021 16:39:02
User entered 'RIGHT ARM pain' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	01 Apr 2021 16:38:02
User opened query 'DM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms.	Coder Import (b) (4)	01 Apr 2021 11:34:25
' (Site from System).		
Data point term sent to Coder	System	25 Mar 2021 00:17:11
User entered 'right arm/shoulder pain'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'Yes (Y)'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'No (N)'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'No (N)'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '13 Mar 2021'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 00:16:26

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'Yes (Y)'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 00:16:26

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'No (N)'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 00:17:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 00:17:18
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:17:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 00:16:26
User entered empty.	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 00:17:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 00:17:18
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:17:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 00:16:26
User entered empty.	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 17:59:04
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 10:28:30
Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate ' answered with 'updated accordingly' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 19:40:13
Signature has been broken.	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 19:39:47
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 19:39:47
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:13:32
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	01 Apr 2021 20:38:31
User entered 'None (NONE)'	Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:16:26

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Mitchell Stern (b) (4)	01 Apr 2021 16:38:53
	(b) (4)	
User entered '1'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '1' reason for change: New Information	Mitchell Stern (b) (4)	01 Apr 2021 16:38:53
	(b) (4)	
User entered '0'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

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Folder: Adverse Events

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Generated On: 11 Aug 2021 23:02:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'participatnt notes increased physical activity recently and onset of right shoulder/arm pain for which he was prescribed a Medrol dose pack which did not have a significant impact on symptoms. At this time, symptoms are improving with increased stretching activities.'	(b) (4)	
	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:16:26

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 00:16:26

US3682018

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:02:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 00:16:26

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Oral herpes, LLT: Oral herpes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:57:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:57:41
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	01 Apr 2021 20:38:31
Data point term sent to Coder	System	25 Mar 2021 00:20:12
User entered 'oral hsv outbreak'	Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Yes (Y)'	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'No (N)'	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'No (N)'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '18 Mar 2021'	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User entered empty.	System	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
Signature has been broken.	(b) (4)	
	Mitchell Stern (b) (4)	21 Apr 2021 21:43:16
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	21 Apr 2021 21:43:16
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'Yes (Y)'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
Signature has been broken.	(b) (4)	
	Mitchell Stern (b) (4)	21 Apr 2021 21:43:16
	(b) (4)	
User entered '19 Mar 2021' reason for change: New Information	Mitchell Stern (b) (4)	21 Apr 2021 21:43:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User entered empty.	System	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'No (N)'	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '0'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '0'	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '0'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '0'	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '0'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '0'	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Not Related (NOT RELATED)'	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Not Related (NOT RELATED)'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 17:59:04
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 10:28:42
Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate ' answered with 'updated accordingly' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 19:41:33
Signature has been broken.	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 19:41:15
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 19:41:15
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:14:03
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	01 Apr 2021 20:38:31
User entered 'None (NONE)'	Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 17:59:04
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 10:28:44
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated accordingly' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 19:41:50
Signature has been broken.	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 19:41:15
User entered '0' reason for change: Per Query Resolution	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 19:41:15
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:47:34
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	01 Apr 2021 20:38:31
User entered '1'	Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 17:59:04
Signature has been broken.	(b) (4)	
	Mitchell Stern (b) (4)	05 Apr 2021 19:41:15
User entered '1' reason for change: Per Query Resolution	(b) (4)	
	Mitchell Stern (b) (4)	05 Apr 2021 19:41:15
User signature succeeded.	(b) (4)	
	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '0'	(b) (4)	
	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '0'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
Signature has been broken.	(b) (4)	
	Mitchell Stern (b) (4)	21 Apr 2021 21:43:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Mitchell Stern (b) (4)	21 Apr 2021 21:43:16
User signature succeeded.	(b) (4)	
	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	
	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'patient reports having left lip "cold" sore and taking valtrex over two days, as prescribed when he visited urgent care'	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User entered '0'	System	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35
User entered '1'	System	25 Mar 2021 00:19:59

US3682018

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:35

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 16:37:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 16:37:37
Data point term sent to Coder	System	01 Apr 2021 16:37:01
User entered 'Right shoulder pain'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'No (N)'	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:36:56

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'No (N)'	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:36:56

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '13 Mar 2021'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 16:36:56

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 16:36:56

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:36:56

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:36:56

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'I'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	01 Apr 2021 16:36:56
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Apr 2021 16:36:56

US3682018

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:02:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 16:36:56

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Animal bite, LLT: Dog bite - version MedDRA\\23.0.	Coder Import (b) (4)	25 Apr 2021 13:06:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Apr 2021 13:06:55
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
Data point term sent to Coder	System (b) (4)	21 Apr 2021 21:42:06
User entered 'Left hand wound secondary to dog bite'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '18 Apr 2021'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 21:42:02

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 21:42:02

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Mitchell Stern (b) (4)	21 Apr 2021 21:42:02

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '1'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Mitchell Stern (b) (4)	21 Apr 2021 21:42:02

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:42:02
	(b) (4)	

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
User entered 'Pt said that his skin barrier was broken.The pt denied symptoms, including pain, secondary to the dog bite.'	(b) (4) Mitchell Stern (b) (4) (b) (4)	21 Apr 2021 21:42:02

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Apr 2021 21:42:02

US3682018

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 23:02:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 21:42:02

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 23:02:48

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:53:47
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:59:37
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:07

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:00:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:19:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:19:36
Data point term sent to Coder	System	26 Aug 2020 22:19:37
User entered 'Multivitamin'	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:00:36
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:00:38
User entered 'Supplement'	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:00:41
User entered '1'	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:00:45
User entered 'tablet (TABLET)'	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:00:47
User entered empty.	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:00:49
User entered 'once daily (QD)'	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:00:52
User entered empty.	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:00:55
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:00:57
User entered empty.	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:00:59
User entered empty.	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:01:01
User entered 'I'	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:01:07
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:01:11
User entered empty.	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:01:13
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 22:18:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 22:18:46
User entered 'No (N)' reason for change: Data Entry Error	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:46
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 22:18:38
User entered empty.	Jesse Clark (b) (4) (b) (4)	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 22:18:38

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:01:20
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) (b) (4)	06 Feb 2021 01:11:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 01:11:28
Data point term sent to Coder	System	06 Feb 2021 00:54:31
User entered 'Azithromycin'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:01:22
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:01:24
User entered 'Strep throat'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:01:31
User entered '500'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:01:35
User entered 'mg (mg)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:01:38
User entered empty.	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User closed query 'This frequency is not one of the choices in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:18
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 23:20:16
Query 'This frequency is not one of the choices in source document. Please verify and update accordingly.' answered with 'Entry modified as requested.' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 21:33:26
User entered 'other (OTHER)' reason for change: Per Query Resolution	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 21:33:05
User opened query 'This frequency is not one of the choices in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 22:02:38
User entered 'once (ONCE)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:12
DataPoint Un-verified.	Jesse Clark (b) (4)	22 Feb 2021 21:33:05
User entered 'Once' reason for change: Per Query Resolution	(b) (4) Jesse Clark (b) (4)	22 Feb 2021 21:33:05
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:02:42
User entered empty.	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:02:57
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:02:59
User entered empty.	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:03:11
User entered '3 Feb 2021'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:03:13
User entered '0'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:03:20
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:03:23
User entered '3 Feb 2021'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:03:25
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User entered empty.	System	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User entered empty.	System	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:19
User entered empty.	System	06 Feb 2021 00:54:22

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:03:42
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) (b) (4)	06 Feb 2021 00:56:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 00:56:52
Data point term sent to Coder	System	06 Feb 2021 00:55:31
User entered 'Azithromycin'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:03:45
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:03:49
User entered 'Strep throat'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:03:55
User entered '250'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:03:59
User entered 'mg (mg)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:04:29
User entered empty.	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:54
User closed query 'This frequency is not one of the choices in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 23:20:42
Query 'This frequency is not one of the choices in source document. Please verify and update accordingly.' answered with 'Once daily is a choice in the source document.' (Site from CRA).	Jesse Clark (b) (4) (b) (4)	22 Feb 2021 21:34:30
User opened query 'This frequency is not one of the choices in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 22:04:27
User entered 'once daily (QD)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:04:31
User entered empty.	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:04:34
User entered 'Oral (ORAL)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:04:36
User entered empty.	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:04:42
User entered '4 Feb 2021'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:04:44
User entered '0'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:04:46
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	17 Feb 2021 19:06:40
User entered 'Yes (Y)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:04:49
User entered '7 Feb 2021' reason for change: New Information	Mitchell Stern (b) (4)	17 Feb 2021 19:06:40
User entered empty.	Jesse Clark (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:04:51
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User entered '1'	System	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User entered '1'	System	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:23
User entered '804 (804)'	System	06 Feb 2021 00:55:00

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE, PRODUCTS YNOM: MEDROL DOSEPAK - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:55:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:55:46
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	01 Apr 2021 20:38:31
Data point term sent to Coder	System	25 Mar 2021 00:24:12
User entered 'medrol dose pack (solumedrol, tapering dose)'	Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'No (N)'	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:23:49
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'right arm/shoulder pain'	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 17:59:04
User closed query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=mg tapering dose. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 07:28:03
Query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=mg tapering dose. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' answered with 'updated' (Site from DM).	Oladunni Adeyiga (b) (4)	07 Apr 2021 16:41:27
Signature has been broken.	(b) (4) Oladunni Adeyiga (b) (4)	07 Apr 2021 16:41:03
User entered 'UNK/UNKOWN' reason for change: Data Entry Error	(b) (4) Oladunni Adeyiga (b) (4)	07 Apr 2021 16:41:03
User opened query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=mg tapering dose. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 07:12:02
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'other'	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	25 Mar 2021 00:24:34
User entered 'Other (OTHER)' reason for change: Data Entry Error	Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:24:34
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	25 Mar 2021 00:23:49
User entered 'mg (mg)'	Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'TAPERING DOSE IN MILLIGRAMS.' reason for change: New Information	Jesse Clark (b) (4)	25 Mar 2021 18:38:43
User entered 'TAPERING DOSE in milligrams. PARTICIPANT REPORTS NOT BEING SURE WHEN HE STOPPED TAKING THIS MEDICATION.' reason for change: Data Entry Error	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:24:34
User entered 'tapering dose. participant reports not being sure when he stopped taking this medication.'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'once daily (QD)'	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:23:49
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Oral (ORAL)'	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '18 Mar 2021'	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:23:49
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '0'	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'No (N)'	(b) (4) Oladunni Adeyiga (b) (4) (b) (4)	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	
	System	25 Mar 2021 18:38:14
User entered '23 Mar 2021' reason for change: Data Entry Error	Jesse Clark (b) (4)	25 Mar 2021 18:38:14
	(b) (4)	
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	25 Mar 2021 00:23:49
User entered 'UN Mar 2021'	Oladunni Adeyiga (b) (4)	25 Mar 2021 00:23:49
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'No (N)'	(b) (4) Oladunni Adeyiga (b) (4)	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User entered '1'	System	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User entered '1'	System	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:26
User entered '804 (804)'	System	25 Mar 2021 00:23:49

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 16:43:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 16:43:27
Data point term sent to Coder	System	01 Apr 2021 16:43:05
User entered 'Valtrex'	Mitchell Stern (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'No (N)'	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Oral HSV Outbreak'	(b) (4) Mitchell Stern (b) (4) (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'unknown'	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'mg (mg)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'twice daily (BID)'	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'Oral (ORAL)'	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered empty.	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '18 Mar 2021'	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '0'	(b) (4) Mitchell Stern (b) (4) (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'No (N)'	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered '19 Mar 2021'	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
User entered 'No (N)'	(b) (4) Mitchell Stern (b) (4)	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User entered '2'	System	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User entered '1'	System	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:32
User entered '804 (804)'	System	01 Apr 2021 16:43:04

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Apr 2021 05:24:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:24:52
Data point term sent to Coder	System	21 Apr 2021 21:45:08
User entered 'Doxycycline'	Mitchell Stern (b) (4) (b) (4)	21 Apr 2021 21:44:44

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'Left hand wound secondary to dog bite'	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '100'	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'twice daily (BID)' reason for change: New Information	Mitchell Stern (b) (4)	21 Apr 2021 21:46:35
	(b) (4)	
User entered 'once daily (QD)'	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '19 Apr 2021'	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	21 Apr 2021 21:44:44
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 21:46:35
User entered '1'	System	21 Apr 2021 21:44:44

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 21:44:44

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 21:44:44

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Apr 2021 05:54:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:54:52
Data point term sent to Coder	System	21 Apr 2021 21:46:09
User entered 'Metronidazole'	Mitchell Stern (b) (4) (b) (4)	21 Apr 2021 21:45:35

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	21 Apr 2021 21:45:35
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
User entered 'LEFT HAND WOUND SECONDARY TO DOG BITE'	(b) (4) Mitchell Stern (b) (4)	21 Apr 2021 21:45:35

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '500'	Mitchell Stern (b) (4)	21 Apr 2021 21:45:35
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	21 Apr 2021 21:45:35
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:45:35
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'three times daily (TID)' reason for change: New Information	Mitchell Stern (b) (4)	21 Apr 2021 21:46:47
	(b) (4)	
User entered 'once daily (QD)'	Mitchell Stern (b) (4)	21 Apr 2021 21:45:35
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:45:35
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	21 Apr 2021 21:45:35
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:45:35
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '19 Apr 2021'	Mitchell Stern (b) (4)	21 Apr 2021 21:45:35
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	21 Apr 2021 21:45:35
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	21 Apr 2021 21:45:35
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	21 Apr 2021 21:45:35
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:10:01
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	21 Apr 2021 21:45:35
	(b) (4)	

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 21:46:47
User entered '1'	System	21 Apr 2021 21:45:35

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 21:45:35

US3682018

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:02:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 21:45:35

US3682018

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 23:02:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:05:20
User entered 'No (N)'	Jesse Clark (b) (4) (b) (4)	09 Sep 2020 15:49:55

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'USA-US081-2020-MRNA-1273-P301000004'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'Jesse'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'Clark'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 23:48:53

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 23:48:53

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'CA'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 23:48:53

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered 'US'	System	15 Dec 2020 14:03:09

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Dec 2020 00:15:40
User entered '1'	System	15 Dec 2020 14:03:09

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'USA-US081-2020-MRNA-1273-P301000004'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'Jesse'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'Clark'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 23:48:53

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 23:48:53

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'CA'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 23:48:53

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered 'US'	System	15 Dec 2020 14:03:09

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Dec 2020 00:15:40
User entered '1'	System	15 Dec 2020 14:03:09

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 23:02:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
User entered '15/Dec/2020 09:03'	System	15 Dec 2020 14:03:09

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 23:02:48

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)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered 'I'	(b) (4), (b) (6)	15 Dec 2020 14:03:09

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'USA-US081-2020-MRNA-1273-P301000004'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'Jesse'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'Clark'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 23:48:53

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 23:48:53

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'CA'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 23:48:53

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered 'US'	System	15 Dec 2020 14:03:09

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Dec 2020 00:15:40
User entered '1'	System	15 Dec 2020 14:03:09

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 23:02:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
User entered '28/Dec/2020 19:15'	System	29 Dec 2020 00:15:40

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 23:02:48

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)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:34:49
User entered 'I'	(b) (4), (b) (6)	29 Dec 2020 00:15:40

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'USA-US081-2020-MRNA-1273-P301000004'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'No (N)'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'Jesse'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'Clark'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 23:48:53

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 23:48:53

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 14:03:04
User entered 'CA'	System	15 Dec 2020 14:02:47

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 23:48:53

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:38:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:24:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 00:15:29
User entered 'US'	System	15 Dec 2020 14:03:09

US3682018

Folder: SAE USA-US081-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Dec 2020 00:15:40
User entered '1'	System	15 Dec 2020 14:03:09