US3022012 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:54:53

All time stamps listed in this document are displayed in GMT

US3022012

Form: Participant Creation

Data signed: (b) (4) **23 Feb 2021 15:37:01**

Generated On: 11 Aug 2021 21:54:53

Participant ID	US3022012

mRNA-1273-P301 Completion Guidelines

US3022012

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

| Was this visit performed? | Yes ● |
| | No ○ |

Visit date (dd MMM yyyy)	27 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | SCRN |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Date of Birth (MMM yyyy)	(b) (6) 1985
Age	35
Age Units	YEARS
Age (Derived)	35

Sex	
	Female ◯
	Male ⬤

Ethnicity	
	Hispanic or Latino ◯
	Not Hispanic or Latino ⬤
	Not Reported ◯
	Unknown ◯

Race (Check All That Apply)

White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Date of Informed Consent *(dd MMM yyyy)*	27 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020

Protocol Version

- Amendment 1 ●
- Amendment 2 ○
- Amendment 3 ○
- Amendment 4 ○
- Amendment 5 ○

Was participant enrolled in the study?

- Yes ●
- No ○

If No, indicate reason for screen fail

- Withdrew Consent ○
- Inclusion/Exclusion ○
- Cohort Full ○
- Other ○

If reason for screen fail is Other, specify _____

Was this participant screened previously?

- Yes ○
- No ●

If Yes, previous participant number _____

Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **23 Feb 2021 15:37:27**

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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) **23 Feb 2021 15:37:27**

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Were any significant conditions reported? Yes ◯

No ⬤

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **23 Feb 2021 15:37:27**

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Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	27 JUL 2020
Time of assessment *(00:00-23:59)*	10:45 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 10:45
Height *(xxx.x)*	183.5 cm
Weight *(xxx.x)*	111.4 kg
BMI *(xxx.x)*	33.08362 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ○
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:37:27

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   27 JUL 2020

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

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **23 Feb 2021 15:37:27**

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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) **23 Feb 2021 15:37:27**

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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	27 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4)　**23 Feb 2021 15:37:27**

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What was the date of randomization? *(dd MMM yyyy)*	27 JUL 2020
What was the participant's randomization number?	100005

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 ●

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **23 Feb 2021 15:37:27**

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	27 JUL 2020
Time of assessment *(00:00-23:59)*	10:45 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 10:45
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	67 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4)   **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	27 JUL 2020
Time of assessment *(00:00-23:59)*	12:57 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 12:57
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	70 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)*	80 mmHg
Diastolic Blood Pressure units	MMHG

Was the physical examination performed?   Yes ◯

                                                                           No ⬤

Date of examination *(dd MMM yyyy)* _____

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

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)*	27 JUL 2020
What was the treatment time? *(00:00-23:59)*	12:09 (24 HR)
Treatment Date and Time (derived)	27 JUL 2020 12:09

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) **23 Feb 2021 15:37:27**

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Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	27 JUL 2020
Collection time *(00:00-23:59)*	11:13 (24 HR)
Collection date and time (derived)	27 JUL 2020 11:13

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Collection date *(dd MMM yyyy)*			27 JUL 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:04	27 JUL 2020 11:04
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:27**

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Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

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	27 JUL 2020 13:01
PC Open Date & Time	27 JUL 2020 12:29
PC Close Date & Time	27 JUL 2020 14:59

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.

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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**	98.4 °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	27 JUL 2020 20:19
PC Open Date & Time	27 JUL 2020 15:54
PC Close Date & Time	28 JUL 2020 11:59

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**	101.7 °F

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

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

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	28 JUL 2020 19:04
PC Open Date & Time	28 JUL 2020 12:00
PC Close Date & Time	29 JUL 2020 11:59

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	99.7 °F

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

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

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	29 JUL 2020 21:23
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

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**	99.1 °F

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

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

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	30 JUL 2020 19:59
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:53

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.

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Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	01 AUG 2020 06:02
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:54:53

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.

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Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	02 AUG 2020 00:08
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

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US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:53

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.

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	03 AUG 2020 00:48
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:53

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	27 JUL 2020 13:01
PC Open Date & Time	27 JUL 2020 12:29
PC Close Date & Time	27 JUL 2020 14:59

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:53

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 JUL 2020 20:20
PC Open Date & Time	27 JUL 2020 15:54
PC Close Date & Time	28 JUL 2020 11:59

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⚪
	Does not interfere with activity ⚫
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ⚪
	Any use of prescription pain reliever or prevents daily activity ⚪
Is there any **REDNESS AT INJECTION SITE**?	Yes ⚪
	No ⚫
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ⚪
	No ⚫
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⚫
	Does not interfere with activity ⚪
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ⚪
	Any use of prescription pain reliever or prevents daily activity ⚪
PC Time Stamp	28 JUL 2020 19:05
PC Open Date & Time	28 JUL 2020 12:00
PC Close Date & Time	29 JUL 2020 11:59

TIMEPOINT	DAY 3

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ◯
	Does not interfere with activity ⬤
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

PC Time Stamp	29 JUL 2020 21:23
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 4

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	30 JUL 2020 20:00
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

TIMEPOINT	DAY 5

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	01 AUG 2020 06:02
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

TIMEPOINT	DAY 6

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

PC Time Stamp	02 AUG 2020 00:09
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	03 AUG 2020 00:48
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:53

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 ○

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯

PC Time stamp	27 JUL 2020 13:01
PC Open Date & Time	27 JUL 2020 12:29
PC Close Date & Time	27 JUL 2020 14:59

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:54:53

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 ◯

FDA-CBER-2022-1614-0016678

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	27 JUL 2020 20:20
PC Open Date & Time	27 JUL 2020 15:54
PC Close Date & Time	28 JUL 2020 11:59

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:53

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 ●

	Yes ◯
PC Time stamp	28 JUL 2020 19:05
PC Open Date & Time	28 JUL 2020 12:00
PC Close Date & Time	29 JUL 2020 11:59

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 ●

	Yes ◯
PC Time stamp	29 JUL 2020 21:23
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

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 ●

FDA-CBER-2022-1614-0016684

	Yes ◯
PC Time stamp	30 JUL 2020 20:00
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

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 ●

	Yes ◯
PC Time stamp	01 AUG 2020 06:02
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:54:53

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 ●

FDA-CBER-2022-1614-0016688

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:54:53

	Yes ◯
PC Time stamp	02 AUG 2020 00:09
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:54:53

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 ●

Yes ◯

PC Time stamp	03 AUG 2020 00:48
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3022012

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	04 AUG 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3022012

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:26**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ●

                                                      No ○

Continuing Flag   1

US3022012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 15:37:08**

Generated On: 11 Aug 2021 21:54:53

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	11 AUG 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3022012

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:08**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3022012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 15:37:26**

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:08**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ●

                                                                No ○

Continuing Flag   1

US3022012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Was this visit performed?	Yes ○
	No ●

Visit date (dd MMM yyyy) _____

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

Folder OID   VISIT2

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ◯
	No ⬤
Date of assessment *(dd MMM yyyy)*	_____
Time of assessment *(00:00-23:59)*	_____
Vital Signs Date and Time (derived)	_____
Temperature *(xxx.x)*	_____
Route of measurement	Oral ◯
	Axillary ◯
	Other ◯
If Other, specify	_____
Pulse *(xxx)*	_____
Pulse units	_____
Respiratory Rate *(xxx)*	_____
Respiratory Rate units	_____
Systolic Blood Pressure *(xxx)*	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure *(xxx)*	_____
Diastolic Blood Pressure units	_____

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Timepoint	Pre-Dose ⚪
	Post-Dose ⬤
Were vital signs assessed?	Yes ⚪
	No ⬤
Date of assessment *(dd MMM yyyy)*	
Time of assessment *(00:00-23:59)*	
Vital Signs Date and Time (derived)	
Temperature *(xxx.x)*	
Route of measurement	Oral ⚪
	Axillary ⚪
	Other ⚪
If Other, specify	
Pulse *(xxx)*	
Pulse units	
Respiratory Rate *(xxx)*	
Respiratory Rate units	
Systolic Blood Pressure *(xxx)*	
Systolic Blood Pressure units	
Diastolic Blood Pressure *(xxx)*	
Diastolic Blood Pressure units	

US3022012

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?   Yes ◯

                                                                                                      No ⬤

Date of examination *(dd MMM yyyy)* _____

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

US3022012
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **23 Feb 2021 15:37:27**
Generated On: 11 Aug 2021 21:54:53

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?   _____

What was the treatment date? *(dd MMM yyyy)*   _____

What was the treatment time? *(00:00-23:59)*   _____

Treatment Date and Time (derived)   _____

Which arm was used to give treatment?   Left Arm ◯

                                                                      Right Arm ◯

What was the frequency of the study treatment dosing?   _____

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

US3022012
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **23 Feb 2021 15:37:27**
Generated On: 11 Aug 2021 21:54:53

Was the sample collected?   Yes ◯

                                                                                  No ⬤

Collection date *(dd MMM yyyy)*

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

Collection date and time (derived)

US3022012
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **23 Feb 2021 15:37:27**
Generated On: 11 Aug 2021 21:54:53

Collection date *(dd MMM yyyy)*

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3022012
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **23 Feb 2021 15:37:27**
Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3022012
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **23 Feb 2021 15:37:26**
Generated On: 11 Aug 2021 21:54:53

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   _____

US3022012

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:26**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3022012

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 15:37:26**

Generated On: 11 Aug 2021 21:54:53

| 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

US3022012

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:26**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?　　　　　　　　　　Yes ●

No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　　1

US3022012
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **23 Feb 2021 15:37:26**
Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:26**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3022012

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT3

US3022012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	23 OCT 2020
Time of assessment *(00:00-23:59)*	14:29 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 14:29
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	85 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022012

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?   Yes ●

No ◯

Date of examination *(dd MMM yyyy)*   23 OCT 2020

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

US3022012

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	23 OCT 2020
Collection time *(00:00-23:59)*	14:35 (24 HR)
Collection date and time (derived)	23 OCT 2020 14:35

US3022012

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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	26 SEP 2020 09:58:42
Patient Cloud Open Date & Time	26 SEP 2020 00:01
Patient Cloud Close Date & Time	30 SEP 2020 23:59

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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	05 OCT 2020 18:53:08
Patient Cloud Open Date & Time	03 OCT 2020 00:01
Patient Cloud Close Date & Time	07 OCT 2020 23:59

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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	14 OCT 2020 11:59:25
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 OCT 2020 14:08:13
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 17:54:58
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 12:05:46
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 113
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-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	14 NOV 2020 00:06:09
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Symptom	
Fever (Temperature ≥ 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 ⬭

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT   **DAY 124**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature $\geq$ 100.4°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 ⬭

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 14:03:12
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 12:00:14
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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	25 DEC 2020 12:14:22
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 11:47:44
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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	06 JAN 2021 00:04:33
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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	15 JAN 2021 12:36:51
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 15:36:18
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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	27 JAN 2021 16:13:06
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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	05 FEB 2021 12:01:49
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⬤
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⬤

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

Fever (Temperature ≥ 100.4°F/38°C)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
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 ⬤
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ⚪
Date and time of submission	10 FEB 2021 17:00:13
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 FEB 2021 12:26:47
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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	28 FEB 2021 17:11:47
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 09:25:38
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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	11 MAR 2021 22:34:22
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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	17 MAR 2021 12:44:28
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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	27 MAR 2021 15:34:32
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 MAR 2021 20:01:16
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 17:41:13
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 12:36:50
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 APR 2021 16:55:44
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

FDA-CBER-2022-1614-0016749

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 APR 2021 12:03:05
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 285**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
Fever (Temperature ≥ 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 ⃝

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 MAY 2021 00:01
Patient Cloud Close Date & Time	09 MAY 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 292**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Fever (Temperature ≥ 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 ⭕

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2021 00:01
Patient Cloud Close Date & Time	16 MAY 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 299

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 MAY 2021 00:01
Patient Cloud Close Date & Time	30 MAY 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

FDA-CBER-2022-1614-0016759

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 JUN 2021 00:01
Patient Cloud Close Date & Time	06 JUN 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 320

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0016761

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 JUN 2021 00:01
Patient Cloud Close Date & Time	13 JUN 2021 23:59

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):

Symptom	
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 ⭕

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2021 00:01
Patient Cloud Close Date & Time	20 JUN 2021 23:59

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):

Symptom	
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 ⚪

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2021 00:01
Patient Cloud Close Date & Time	27 JUN 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ≥ 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 ⃝

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 348**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2021 00:01
Patient Cloud Close Date & Time	11 JUL 2021 23:59

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 355**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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):

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0016773

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 369**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 JUL 2021 00:01
Patient Cloud Close Date & Time	01 AUG 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

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

Symptom	
Fever (Temperature ≥ 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 ○

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 AUG 2021 00:01
Patient Cloud Close Date & Time	08 AUG 2021 23:59

TIMEPOINT   DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
Fever (Temperature ≥ 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 ⃝

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2021 00:01
Patient Cloud Close Date & Time	15 AUG 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 AUG 2021 00:01
Patient Cloud Close Date & Time	22 AUG 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ≥ 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 ⚪

FDA-CBER-2022-1614-0016783

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 404**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2021 00:01
Patient Cloud Close Date & Time	05 SEP 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 411**

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

No ⚪
Yes ⚪

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

No ⚪
Yes ⚪

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

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

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

No ⚪
Yes ⚪

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

Fever (Temperature ≥ 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 ⚪

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

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

Fever (Temperature ≥ 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 ○

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 425**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2021 00:01
Patient Cloud Close Date & Time	26 SEP 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ◯

FDA-CBER-2022-1614-0016793

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2021 00:01
Patient Cloud Close Date & Time	03 OCT 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 439**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0016795

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 446**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬡ Yes ⬡
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬡ Yes ⬡
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬡
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬡ Yes ⬡

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬡
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬡ Yes ⬡

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ≥ 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 ⬭

FDA-CBER-2022-1614-0016799

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 460**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT   **DAY 467**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 NOV 2021 00:01
Patient Cloud Close Date & Time	07 NOV 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ⃝

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 NOV 2021 00:01
Patient Cloud Close Date & Time	14 NOV 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 481**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0016807

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 NOV 2021 00:01
Patient Cloud Close Date & Time	21 NOV 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT **DAY 488**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 NOV 2021 00:01
Patient Cloud Close Date & Time	28 NOV 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT | **DAY 502**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⟳ Yes ⟳
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⟳ Yes ⟳
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⟳
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⟳ Yes ⟳

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

Fever (Temperature ≥ 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 ⟳

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT | DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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):

Symptom	
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 ⚪

FDA-CBER-2022-1614-0016817

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

<table>
<tr><td>TIMEPOINT</td><td style="text-align:right">DAY 523</td></tr>
<tr><td>Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?</td><td style="text-align:right">No ◯
Yes ◯</td></tr>
<tr><td>Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?</td><td style="text-align:right">No ◯
Yes ◯</td></tr>
<tr><td>Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.</td><td style="text-align:right">I confirm I have read this message and will call the study clinic immediately ◯</td></tr>
<tr><td>Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?</td><td style="text-align:right">No ◯
Yes ◯</td></tr>
</table>

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 _____

<table>
<tr><td>Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.</td><td style="text-align:right">I confirm I have read this message and will call the study clinic immediately ◯</td></tr>
<tr><td>Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?</td><td style="text-align:right">No ◯
Yes ◯</td></tr>
</table>

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 530**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0016821

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 JAN 2022 00:01
Patient Cloud Close Date & Time	09 JAN 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ≥ 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 ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ◯

FDA-CBER-2022-1614-0016825

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 551**

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

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

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

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

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

Fever (Temperature ≥ 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 ⬭

FDA-CBER-2022-1614-0016827

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 JAN 2022 00:01
Patient Cloud Close Date & Time	30 JAN 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ◯

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	06 FEB 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ≥ 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 ⃝

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 FEB 2022 00:01
Patient Cloud Close Date & Time	13 FEB 2022 23:59

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

TIMEPOINT DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

FDA-CBER-2022-1614-0016833

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	20 FEB 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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):

Symptom	
Fever (Temperature ≥ 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 ⚪

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 586**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ○

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ○

FDA-CBER-2022-1614-0016837

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	06 MAR 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ◯

FDA-CBER-2022-1614-0016839

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 MAR 2022 00:01
Patient Cloud Close Date & Time	13 MAR 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 600

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	20 MAR 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	27 MAR 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature ≥ 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 ⬭

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 621**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	17 APR 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	24 APR 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ≥ 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 ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT **DAY 649**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	08 MAY 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ≥ 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 ◯

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 MAY 2022 00:01
Patient Cloud Close Date & Time	15 MAY 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ≥ 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 ⬭

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	22 MAY 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	29 MAY 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT   DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Symptom	
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 ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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):

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0016865

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	12 JUN 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 691**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ≥ 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 ⭕

FDA-CBER-2022-1614-0016869

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 726**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

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

Symptom	
Fever (Temperature ≥ 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 ⚪

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	24 JUL 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 733**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	07 AUG 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 747**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ⚪

FDA-CBER-2022-1614-0016885

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	21 AUG 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0016887

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	28 AUG 2022 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 768

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

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

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

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

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

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

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

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	04 SEP 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 ≥ 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 ○

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature ≥ 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 ⃝

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	18 SEP 2022 23:59

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 789**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT	**DAY 796**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0016897

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

US3022012

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:54:53

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 17:11:55

US3022012

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3022012

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3022012

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 15:37:08**

Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 NOV 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments _____

US3022012

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:08**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ○

Continuing Flag   1

US3022012

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 15:37:08**

Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	24 DEC 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3022012

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:08**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ●

                                                                 No ◯

Continuing Flag   1

US3022012

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 15:37:08**

Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	21 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3022012

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:08**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ●

                                                                      No ○

Continuing Flag   1

US3022012
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **25 Mar 2021 22:59:02**
Generated On: 11 Aug 2021 21:54:53

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	09 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT4

US3022012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	09 FEB 2021
Time of assessment *(00:00-23:59)*	15:16 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 15:16
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	95 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0016909

US3022012

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 22:59:02

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   09 FEB 2021

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

US3022012

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **25 Mar 2021 22:59:02**

Generated On: 11 Aug 2021 21:54:53

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	09 FEB 2021
Collection time *(00:00-23:59)*	14:44 (24 HR)
Collection date and time (derived)	09 FEB 2021 14:44

US3022012

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **25 Mar 2021 22:59:02**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ●

                                                                                                    No ○

Continuing Flag   1

US3022012
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?   Yes ●

                                                                          No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*   19 MAR 2021

Please select one status for the follow-up contact   Contact Made ●

                                                          Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3022012

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3022012
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

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 _____

Is the participant continuing to the next visit? Yes ◯

No ◯

Continuing Flag _____

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Date of Contact	03 AUG 2020
Time of Contact	15:14
Date and Time of Contact (derived)	03 AUG 2020 15:14
Type of Contact	Clinic Visit - Scheduled ◯
	Clinical Visit - Unscheduled ◯
	Safety Call ●
	Convalescent Tele-visit ◯
Has the subject reported symptoms of SARS-COV-2?	Yes ●
	No ◯

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	05 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.5 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Not Done ◯

Fatigue

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ◯

Mild ⬤

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

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 ○

FDA-CBER-2022-1614-0016921

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	06 AUG 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	97.9 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

FDA-CBER-2022-1614-0016923

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Not Done ⬭

Fatigue

- None ⬤
- Mild ⬭
- Moderate ⬭
- Severe ⬭
- Not Done ⬭

Muscle Aches (Myalgia)

- None ⬤
- Mild ⬭
- Moderate ⬭
- Severe ⬭
- Not Done ⬭

Body Aches

- None ⬤
- Mild ⬭
- Moderate ⬭
- Severe ⬭
- Not Done ⬭

Headache

- None ⬤
- Mild ⬭
- Moderate ⬭
- Severe ⬭
- Not Done ⬭

New Loss of Taste

- None ⬤
- Mild ⬭
- Moderate ⬭
- Severe ⬭
- Not Done ⬭

New Loss of Smell

- None ⬤
- Mild ⬭
- Moderate ⬭
- Severe ⬭
- Not Done ⬭

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

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 ○

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

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	Day 33 ⭘
	Day 34 ⭘
	Day 35 ⭘
	Day 36 ⭘
	Day 37 ⭘
	Day 38 ⭘
	Day 39 ⭘
	Day 40 ⭘
Date	07 AUG 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.7 F
Chills	None ⬤
	Mild ⭘
	Moderate ⭘
	Severe ⭘
	Not Done ⭘
Cough	None ⬤
	Mild ⭘
	Moderate ⭘
	Severe ⭘
	Not Done ⭘
Shortness of Breath	None ⬤
	Mild ⭘
	Moderate ⭘
	Severe ⭘
	Not Done ⭘
Difficulty Breathing	None ⬤
	Mild ⭘
	Moderate ⭘
	Severe ⭘

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Not Done ⬭

Fatigue
- None ⬤
- Mild ⬭
- Moderate ⬭
- Severe ⬭
- Not Done ⬭

Muscle Aches (Myalgia)
- None ⬤
- Mild ⬭
- Moderate ⬭
- Severe ⬭
- Not Done ⬭

Body Aches
- None ⬤
- Mild ⬭
- Moderate ⬭
- Severe ⬭
- Not Done ⬭

Headache
- None ⬤
- Mild ⬭
- Moderate ⬭
- Severe ⬭
- Not Done ⬭

New Loss of Taste
- None ⬤
- Mild ⬭
- Moderate ⬭
- Severe ⬭
- Not Done ⬭

New Loss of Smell
- None ⬤
- Mild ⬭
- Moderate ⬭
- Severe ⬭
- Not Done ⬭

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

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 ○

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	08 AUG 2020
Assessment Not Done	False
O2 Saturation	92 %
O2 Saturation Units	%
Temperature	97.3 F

Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia) None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

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 ○

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

Day 33	◯
Day 34	◯
Day 35	◯
Day 36	◯
Day 37	◯
Day 38	◯
Day 39	◯
Day 40	◯

Date	09 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	99.3 F

Chills
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Cough
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Shortness of Breath
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Difficulty Breathing
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯

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Not Done ◯

Fatigue
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Muscle Aches (Myalgia)
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Body Aches
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Headache
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

New Loss of Taste
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

New Loss of Smell
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

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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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	10 AUG 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	97.9 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Not Done ○

Fatigue — None ⬤

Mild ○

Moderate ○

Severe ○

Not Done ○

Muscle Aches (Myalgia) — None ⬤

Mild ○

Moderate ○

Severe ○

Not Done ○

Body Aches — None ⬤

Mild ○

Moderate ○

Severe ○

Not Done ○

Headache — None ⬤

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Taste — None ⬤

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Smell — None ⬤

Mild ○

Moderate ○

Severe ○

Not Done ○

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 03 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

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US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	11 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.1 F

Chills	
	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Cough	
	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Shortness of Breath	
	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Difficulty Breathing	
	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue · · · None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia) · · · None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches · · · None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache · · · None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste · · · None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell · · · None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

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 ○

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	12 AUG 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	97.4 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Muscle Aches (Myalgia)
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Body Aches
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Headache
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

New Loss of Taste
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

New Loss of Smell
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

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 ○

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	13 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.9 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue   None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)   None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches   None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache   None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste   None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell   None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

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 ○

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	14 AUG 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.3 F

Chills
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Cough
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Shortness of Breath
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Difficulty Breathing
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯

Not Done ◯

Fatigue None ●
Mild ◯
Moderate ◯
Severe ◯

Not Done ◯

Muscle Aches (Myalgia) None ●
Mild ◯
Moderate ◯
Severe ◯

Not Done ◯

Body Aches None ●
Mild ◯
Moderate ◯
Severe ◯

Not Done ◯

Headache None ●
Mild ◯
Moderate ◯
Severe ◯

Not Done ◯

New Loss of Taste None ●
Mild ◯
Moderate ◯
Severe ◯

Not Done ◯

New Loss of Smell None ●
Mild ◯
Moderate ◯
Severe ◯

Not Done ◯

FDA-CBER-2022-1614-0016956

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 ○

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

Day 33	◯
Day 34	◯
Day 35	◯
Day 36	◯
Day 37	◯
Day 38	◯
Day 39	◯
Day 40	◯

Date	15 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.3 F

Chills
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Cough
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Shortness of Breath
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Difficulty Breathing
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯

Not Done ◯

Fatigue

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Muscle Aches (Myalgia)

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Body Aches

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Headache

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

New Loss of Taste

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

New Loss of Smell

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

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 ○

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	16 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97.7 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Not Done ○

Fatigue
None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Muscle Aches (Myalgia)
None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Body Aches
None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Headache
None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Taste
None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Smell
None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

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 ○

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	17 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.4 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

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	○

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	18 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.7 F

Chills	
	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Cough	
	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Shortness of Breath	
	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Difficulty Breathing	
	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Muscle Aches (Myalgia) None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Body Aches None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Headache None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Taste None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Smell None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

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 ○

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	19 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.2 F
Chills	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Cough	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭

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Not Done ◯

Fatigue None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia) None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

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 ○

FDA-CBER-2022-1614-0016977

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

FDA-CBER-2022-1614-0016978

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	20 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97.9 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Not Done ○

Fatigue None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Muscle Aches (Myalgia) None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Body Aches None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Headache None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Taste None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Smell None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

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 ○

FDA-CBER-2022-1614-0016981

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	21 AUG 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.1 F

Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ⬭

Fatigue   None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Muscle Aches (Myalgia)   None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Body Aches   None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Headache   None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

New Loss of Taste   None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

New Loss of Smell   None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

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 ○

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	22 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.9 F
Chills	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ●
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ⬭

Fatigue
None ⬤
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Muscle Aches (Myalgia)
None ⬤
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Body Aches
None ⬤
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Headache
None ⬤
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

New Loss of Taste
None ⬤
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

New Loss of Smell
None ⬤
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

FDA-CBER-2022-1614-0016988

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 ○

FDA-CBER-2022-1614-0016989

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	23 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.1 F
Chills	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Cough	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭

Not Done ◯

Fatigue

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

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 ○

Symptom Day

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

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	24 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.8 F
Chills	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Cough	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭

FDA-CBER-2022-1614-0016995

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (20)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Not Done ◯

Fatigue

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

PRODUCTION RELEASE (v12.003 EAB) (1725)

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 ○

FDA-CBER-2022-1614-0016997

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

FDA-CBER-2022-1614-0016998

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	25 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.1 F

Chills
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Cough
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Shortness of Breath
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Difficulty Breathing
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

	Not Done ⬭
Fatigue	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Muscle Aches (Myalgia)	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Body Aches	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Headache	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
New Loss of Taste	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
New Loss of Smell	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

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 ○

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	26 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.2 F
Chills	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Cough	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭

Not Done ◯

Fatigue

None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Muscle Aches (Myalgia)

None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Body Aches

None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Headache

None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Taste

None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Smell

None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

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 ○

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (23)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (23)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	27 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.3 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia) None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

FDA-CBER-2022-1614-0017008

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (23)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

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 ○

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (24)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ⃝
	Day 34 ⃝
	Day 35 ⃝
	Day 36 ⃝
	Day 37 ⃝
	Day 38 ⃝
	Day 39 ⃝
	Day 40 ⃝
Date	28 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.9 F
Chills	None ⬤
	Mild ⃝
	Moderate ⃝
	Severe ⃝
	Not Done ⃝
Cough	None ⬤
	Mild ⃝
	Moderate ⃝
	Severe ⃝
	Not Done ⃝
Shortness of Breath	None ⬤
	Mild ⃝
	Moderate ⃝
	Severe ⃝
	Not Done ⃝
Difficulty Breathing	None ⬤
	Mild ⃝
	Moderate ⃝
	Severe ⃝

Not Done ⬭

Fatigue

None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Muscle Aches (Myalgia)

None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Body Aches

None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Headache

None ⬭

Mild ⬤

Moderate ⬭

Severe ⬭

Not Done ⬭

New Loss of Taste

None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

New Loss of Smell

None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (24)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

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 ○

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (25)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	29 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.1 F
Chills	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Cough	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (25)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Not Done ⚪

Fatigue

None ⬤

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

Muscle Aches (Myalgia)

None ⬤

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

Body Aches

None ⬤

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

Headache

None ⚪

Mild ⬤

Moderate ⚪

Severe ⚪

Not Done ⚪

New Loss of Taste

None ⬤

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

New Loss of Smell

None ⬤

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

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 ○

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	30 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.3 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia) None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache None ◯

Mild ⬤

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

FDA-CBER-2022-1614-0017020

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 ○

Symptom Day

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

FDA-CBER-2022-1614-0017022

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (27)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	04 AUG 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	97.5 F

Chills
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Cough
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Shortness of Breath
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Difficulty Breathing
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯

Not Done ◯

Fatigue
None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Muscle Aches (Myalgia)
None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Body Aches
None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Headache
None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Taste
None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Smell
None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (27)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

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 ◯

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (30)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	31 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.9 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (30)
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

Not Done ○

Fatigue None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Muscle Aches (Myalgia) None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Body Aches None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Headache None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Taste None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Smell None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (30)

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

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 ○

FDA-CBER-2022-1614-0017029

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **23 Feb 2021 15:37:02**
Generated On: 11 Aug 2021 21:54:53

Date of Visit	04 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ●
	No ○
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ●
	No ○
Date of Test	04 AUG 2020
Type of Test Performed	Nasopharyngeal Swab ○
	Nasal Swab ●
	Saliva Test ○
	Other ○
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ○
	No ●
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ○
	No ○
COVID-19 Positive (CSA Programming Field Only)	1

Did the subject have Respiratory Rates $\geq$ 30 per Minute?   Yes ⚪   No ⚫

If Yes, provide:

  Start Date

  End Date

  Respiratory Rate

Did the subject have Heart Rate $\geq$ 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   08 AUG 2020

  End Date   08 AUG 2020

  Oxygen Saturation   92 %

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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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	

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   _____

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **23 Feb 2021 15:37:02**
Generated On: 11 Aug 2021 21:54:53

Generate Next COVID-19 Assessment   Yes ◯

                                                                      No ⬤

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) **05 Mar 2021 22:53:25**

Generated On: 11 Aug 2021 21:54:53

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	06 AUG 2020
Day 5	Yes	08 AUG 2020
Day 7	Yes	10 AUG 2020
Day 9	Yes	12 AUG 2020
Day 14	Yes	17 AUG 2020
Day 21	Yes	24 AUG 2020
Day 28	Yes	31 AUG 2020

US3022012

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 15:37:06**

Generated On: 11 Aug 2021 21:54:53

Was this visit performed?	Yes ●
	No ◯
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ●
Folder OID	SICKD1

US3022012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) **23 Feb 2021 15:37:06**

Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	04 AUG 2020
Time of assessment *(00:00-23:59)*	09:56 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 09:56
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0017037

US3022012

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) **23 Feb 2021 15:37:06**

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?   Yes ⬤

                                                           No ◯

Date of examination *(dd MMM yyyy)*   04 AUG 2020

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

US3022012

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) **23 Feb 2021 15:37:06**

Generated On: 11 Aug 2021 21:54:53

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ●
	No ◯
	NA (COVID-19 Negative) ◯

Date of Collection	04 AUG 2020

US3022012

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) **23 Feb 2021 15:37:01**

Generated On: 11 Aug 2021 21:54:53

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	SICKD28

US3022012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) **23 Feb 2021 15:37:02**

Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	31 AUG 2020
Time of assessment *(00:00-23:59)*	14:30 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:30
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	89 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0017041

US3022012

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) **23 Feb 2021 15:37:01**

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?　　　　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Date of examination *(dd MMM yyyy)*　　　　　　　　　　　　31 AUG 2020

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

US3022012

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) **23 Feb 2021 15:37:01**

Generated On: 11 Aug 2021 21:54:53

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ●
	No ◯
	NA (COVID-19 Negative) ◯

Date of Collection	31 AUG 2020

US3022012

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:37:06

Generated On: 11 Aug 2021 21:54:53

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	09 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	UNBLND_DECIDE

Date of updated informed consent *(dd MMM yyyy)*	09 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ●
	No ◯
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ◯
	Amendment 6 or later ●
Date of unblinding *(dd MMM yyyy)*	09 FEB 2021
Participant randomization assignment	mRNA-1273 ●
	Placebo ◯
Actual Dose 1	mRNA-1273 ●
	Placebo ◯
	Not Administered ◯
Actual Dose 2	mRNA-1273 ◯
	Placebo ◯
	Not Administered ●
Will participant receive mRNA-1273?	Yes ●
	No ◯
Placebo Only Flag	
Continuing with mRNA-1273	1

US3022012

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

Form: Vital Signs - Dosing

Data signed: (b) (4) **23 Feb 2021 15:37:06**

Generated On: 11 Aug 2021 21:54:53

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

US3022012

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **23 Feb 2021 15:37:06**

Generated On: 11 Aug 2021 21:54:53

Height	ND - Not Done
Weight	ND - Not Done
BMI *(xxx.x)*	
Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	09 FEB 2021
Time of assessment *(00:00-23:59)*	15:16 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 15:16
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	95 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG

US3022012

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:37:06

Generated On: 11 Aug 2021 21:54:53

Height	ND - Not Done
Weight	ND - Not Done
BMI *(xxx.x)*	
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	09 FEB 2021
Time of assessment *(00:00-23:59)*	16:26 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 16:26
Temperature *(xxx.x)*	37.0 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	99 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG

US3022012

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

Form: Physical Examination

Data signed: (b) (4) **23 Feb 2021 15:37:06**

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?   Yes ●

                                                                                     No ◯

Date of examination *(dd MMM yyyy)*   09 FEB 2021

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

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)*	09 FEB 2021
What was the treatment time? *(00:00-23:59)*	15:55 (24 HR)
Treatment Date and Time (derived)	09 FEB 2021 15:55
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

| Was the sample collected? | Yes ● |
| | No ◯ |

Collection date *(dd MMM yyyy)*	09 FEB 2021
Collection time *(00:00-23:59)*	14:44 (24 HR)
Collection date and time (derived)	09 FEB 2021 14:44

US3022012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **23 Feb 2021 15:37:06**

Generated On: 11 Aug 2021 21:54:53

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	09 FEB 2021
Collection time *(00:00 - 23:59)*	14:57
Collection Date and Time (derived)	09 FEB 2021 14:57

US3022012

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

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:06**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3022012

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 FEB 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3022012

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **23 Feb 2021 15:37:27**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ●

     No ○

Continuing Flag	1
OLD29 Placebo Flag	1

US3022012

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) **25 Mar 2021 22:59:02**

Generated On: 11 Aug 2021 21:54:53

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	09 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	OLD29

Were vital signs assessed?	Yes ◯
	No ◯

Date of assessment *(dd MMM yyyy)* _____

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

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

Route of measurement	Oral ◯
	Axillary ◯
	Other ◯

If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **25 Mar 2021 22:59:02**

Generated On: 11 Aug 2021 21:54:53

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	09 MAR 2021
Time of assessment *(00:00-23:59)*	15:18 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 15:18
Temperature *(xxx.x)*	36.4 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	82 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	77 mmHg
Diastolic Blood Pressure units	MMHG

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **25 Mar 2021 22:59:02**

Generated On: 11 Aug 2021 21:54:53

Timepoint

Pre-Dose ◯

Post-Dose ⬤

Were vital signs assessed?

Yes ◯

No ⬤

Date of assessment *(dd MMM yyyy)* _____

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

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

Route of measurement

Oral ◯

Axillary ◯

Other ◯

If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

US3022012

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) **25 Mar 2021 22:59:02**

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?   Yes ●

                                                                           No ○

Date of examination *(dd MMM yyyy)*   09 MAR 2021

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

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   SUBJECT GOT DOSED AT OL
Participant, Protocol Deviation, or Other, specify   VISIT

What was the study treatment?   _____

What was the treatment date? *(dd MMM yyyy)*   _____

What was the treatment time? *(00:00-23:59)*   _____

Treatment Date and Time (derived)   _____

Which arm was used to give treatment?   Left Arm ◯
                                                                 Right Arm ◯

What was the frequency of the study treatment dosing?   _____

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

Was the sample collected?   Yes ◯
                                                                             No ◯

Collection date *(dd MMM yyyy)*

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

Collection date and time (derived)

FDA-CBER-2022-1614-0017062

US3022012

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) **25 Mar 2021 22:59:02**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3022012
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Data signed: (b) (4) **13 Apr 2021 22:09:53**
Generated On: 11 Aug 2021 21:54:53

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 MAR 2021
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3022012

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3022012

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	13 APR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	OLD57

US3022012

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	13 APR 2021
Time of assessment *(00:00-23:59)*	14:50 (24 HR)
Vital Signs Date and Time (derived)	13 APR 2021 14:50
Temperature *(xxx.x)*	36.8 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022012

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) **13 Apr 2021 22:09:53**

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?   Yes ●

                                                           No ○

Date of examination *(dd MMM yyyy)*   13 APR 2021

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

Was the sample collected?	Yes	●
	No	○

Collection date *(dd MMM yyyy)*	13 APR 2021
Collection time *(00:00-23:59)*	15:01 (24 HR)
Collection date and time (derived)	13 APR 2021 15:01

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **23 Feb 2021 15:37:01**

Generated On: 11 Aug 2021 21:54:53

Did the participant experience any adverse events?   Yes ⬤

                                                                     No ◯

If Yes, enter details on the Adverse Events form.

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **23 Feb 2021 15:37:01**

Generated On: 11 Aug 2021 21:54:53

AEID	USA-US051-2020-MRNA-1273-P30 1000002
Adverse event	COVID-19

Was this a medically-attended AE? Yes ● No ○

Was this a Solicited Adverse Reaction? Yes ○ No ●

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

Start date *(dd MMM yyyy)*	27 JUL 2020
Start time *(00:00-23:59)*	08:00 (24 HR)
AE start date and time (derived)	27 JUL 2020 08:00

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 ○

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **23 Feb 2021 15:37:01**

Generated On: 11 Aug 2021 21:54:53

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 ●
	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	SUBJECT ONLY TAKEN TYLENOL FOR HEADACHE. SUBJECT DON'T HAVE ANY MEDICAL HISTORY TO ADD.
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **23 Feb 2021 15:37:01**

Generated On: 11 Aug 2021 21:54:53

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

No ◯

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **23 Feb 2021 15:37:01**

Generated On: 11 Aug 2021 21:54:53

Name of Medication	TYLENOL

Prophylaxis	Yes ⬭
	No ⬤

Indication	POSSIBLE COVID-19

Dose per administration	500

Dose unit	mg ⬤
	ug ⬭
	mL ⬭
	g ⬭
	IU ⬭
	tablet ⬭
	capsule ⬭
	puff ⬭
	Other ⬭

If dose unit is Other, specify	

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

If frequency is Other, specify	

Route of administration	Oral ⬤
	Topical ⬭
	Subcutaneous ⬭
	Transdermal ⬭
	Intraocular ⬭

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	28 JUL 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	01 AUG 2020
Was this medication taken for solicited event?	Yes ⬤
	No ◯
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3022012

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **23 Feb 2021 15:37:01**

Generated On: 11 Aug 2021 21:54:53

Were any concomitant procedures performed?   Yes ◯

No ⬤

If yes, please complete Concomitant Procedures form.

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) **23 Feb 2021 15:37:05**

Generated On: 11 Aug 2021 21:54:53

Visit	
	Screening ⬭
	Visit 1 Day 1 ⬭
	Visit 2 Day 29 ⬤
	Visit 3 Day 57 ⬭
	Visit 4 Day 209 ⬭
	Visit 5 Day 394 ⬭
	Visit 6 Day 759 ⬭

Case Report Form

Visit Date	True
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	True
Vital Signs - Dosing	True
Physical Examination	False
Central Laboratory - Nasopharyngeal Swab	True
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	True
Immunogenicity Assessment	True
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	False
Dosing Discontinuation	False

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) **23 Feb 2021 15:37:05**

Generated On: 11 Aug 2021 21:54:53

End of Study / Study Discontinuation	False
All	False

Date of missed or out of window visit or assessment	31 AUG 2020

Category

Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	True
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	

Description of Relationship to COVID-19

Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	True
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	False
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3022012
Folder: End of Study (1)
Form: Dosing Discontinuation
Data signed: (b) (4) **23 Feb 2021 15:37:06**
Generated On: 11 Aug 2021 21:54:53

Date of dosing discontinuation (dd MMM yyyy)	02 AUG 2020

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

_____

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 ◯

FDA-CBER-2022-1614-0017080

SAEID	USA-US051-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form (1)
Data signed: (b) (4) **23 Feb 2021 15:37:07**
Generated On: 11 Aug 2021 21:54:53

SAEID	USA-US051-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	28/AUG/2020 13:36
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

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form (2)
Data signed: (b) (4) **23 Feb 2021 15:37:07**
Generated On: 11 Aug 2021 21:54:53

SAEID	USA-US051-2020-MRNA-1273-P30 1000002
Serious	Yes ⭘ No ⬤
Death	Yes ⭘ No ⬤
Life threatening	Yes ⭘ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ⭘ No ⬤
Persistent or significant disability or incapacity	Yes ⭘ No ⬤
Congenital anomaly or birth defect	Yes ⭘ No ⬤
Other medically important event	Yes ⭘ No ⬤
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/SEP/2020 13:30
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

US3022012

Folder: SAE USA-US051-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) **23 Feb 2021 15:37:07**

Generated On: 11 Aug 2021 21:54:53

SAEID	USA-US051-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ●
Death	Yes ◯ No ●
Life threatening	Yes ◯ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ●
Persistent or significant disability or incapacity	Yes ◯ No ●
Congenital anomaly or birth defect	Yes ◯ No ●
Other medically important event	Yes ◯ No ●
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/SEP/2020 08:52
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

US3022012

Folder: SAE USA-US051-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) **23 Feb 2021 15:37:07**

Generated On: 11 Aug 2021 21:54:53

SAEID	USA-US051-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/SEP/2020 07:36
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

SAEID	USA-US051-2020-MRNA-1273-P30 1000002
Serious	Yes ⚪ No ⚫
Death	Yes ⚪ No ⚫
Life threatening	Yes ⚪ No ⚫
Requires inpatient or prolongation of existing Hospitalization	Yes ⚪ No ⚫
Persistent or significant disability or incapacity	Yes ⚪ No ⚫
Congenital anomaly or birth defect	Yes ⚪ No ⚫
Other medically important event	Yes ⚪ No ⚫
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/SEP/2020 16:31
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

Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form (6)
Data signed: (b) (4) **23 Feb 2021 15:37:07**
Generated On: 11 Aug 2021 21:54:53

SAEID	USA-US051-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/OCT/2020 18:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3022012 (Prod: Meridian Clinical Research-Savannah)

US3022012

Form: Participant Creation

Generated On: 11 Aug 2021 21:54:53

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:49:31
User entered 'US3022012'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 14:29:42

US3022012
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:54:44

US3022012
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 14:29:43

US3022012
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:54:44

US3022012
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User entered 'SCRN'	System	27 Jul 2020 16:54:44

US3022012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:27
User entered (b) (6) 1985'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 14:29:44

US3022012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:53

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '35'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:05

US3022012
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:54:53
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User entered 'YEARS'	System	27 Jul 2020 16:55:05

US3022012
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:54:53
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User entered '35'	System	27 Jul 2020 16:55:27

US3022012
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:54:53
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Male (M)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:05

US3022012
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:54:53
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:05

US3022012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:53

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '1'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:05

US3022012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:53

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:05

US3022012
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:54:53

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:05

US3022012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:53

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:05

US3022012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:53

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:05

US3022012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:05

US3022012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:05

US3022012
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:54:53
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:05

US3022012
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 21:54:53
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:05

US3022012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:53

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '27 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:27

US3022012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:53

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User entered 'Jul 2020'	System	27 Jul 2020 16:55:27

US3022012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:53

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User entered '2020'	System	27 Jul 2020 16:55:27

US3022012
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:54:53
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Amendment 1 (1)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:27

US3022012
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:54:53

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:27

US3022012
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:54:53
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:27

US3022012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:27

FDA-CBER-2022-1614-0017115

US3022012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:53

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:27

Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 21:54:53
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 14:29:43

US3022012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:53

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:05
User entered '1'	System	27 Jul 2020 16:55:33

US3022012

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:54:53

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:55:33

US3022012

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:54:53

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User closed query 'Per CDM: Thank you for your response; however please complete the Concomitant medications page to reflect this information, or explain and reconcile. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:15:42
Query 'Per CDM: Thank you for your response; however please complete the Concomitant medications page to reflect this information, or explain and reconcile. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 22:57:38
User opened query 'Per CDM: Thank you for your response; however please complete the Concomitant medications page to reflect this information, or explain and reconcile. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:12:26
User closed query 'Per CDM: It appears participant is 35 years of age, yet there are no Medical History or Concomitant Medications recorded. Please review, reconcile, and update ALL applicable forms accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:12:14
Query 'Per CDM: It appears participant is 35 years of age, yet there are no Medical History or Concomitant Medications recorded. Please review, reconcile, and update ALL applicable forms accordingly.' answered with 'NO MEDICAL HISTORY. PATIENT IS HEALTHY ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 14:13:34
User opened query 'Per CDM: It appears participant is 35 years of age, yet there are no Medical History or Concomitant Medications recorded. Please review, reconcile, and update ALL applicable forms accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 19:39:50
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:30:04

US3022012
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:01

US3022012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '27 Jul 2020'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '10:45'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:01

US3022012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User entered '27 Jul 2020 10:45'	System	27 Jul 2020 23:31:01

US3022012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '183.5' cm	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:01
DataPoint set to visible.	System	27 Jul 2020 16:55:33

US3022012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '111.4' kg	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:01
DataPoint set to visible.	System	27 Jul 2020 16:55:33

US3022012
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
Amendment Manager: User entered '33.08362'	System	16 Sep 2020 23:36:44
User entered '33.1'	System	27 Jul 2020 23:31:01
DataPoint set to visible.	System	27 Jul 2020 16:55:33

US3022012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User entered 'kg/m2'	System	27 Jul 2020 23:31:01
DataPoint set to visible.	System	27 Jul 2020 16:55:33

US3022012
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User closed query 'Per CDM Re query: Thanks for the response, kindly Remove units for PULSE, RESPIRATORY RATE, SYS BP and DIA BP as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:23:35
Query 'Per CDM Re query: Thanks for the response, kindly Remove units for PULSE, RESPIRATORY RATE, SYS BP and DIA BP as well. Please update accordingly.' answered with 'IT WILL NOT LET ME ERASE THOSE' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:41:28
User opened query 'Per CDM Re query: Thanks for the response, kindly Remove units for PULSE, RESPIRATORY RATE, SYS BP and DIA BP as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:17:12
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:17:00
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the unit should not remain. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 23:00:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Oct 2020 22:59:52

US3022012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:22:50
User entered '98.2' F	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:01

US3022012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Oct 2020 22:59:52
User entered 'Oral (Oral)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:01

US3022012
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:01

US3022012
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Oct 2020 22:59:52
User entered '67'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:01

US3022012
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User entered 'bpm'	System	27 Jul 2020 23:31:01

US3022012
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Oct 2020 22:59:52
User entered '14'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:01

US3022012
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User entered 'breaths/min'	System	27 Jul 2020 23:31:01

US3022012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Oct 2020 22:59:52
User entered '121'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:01

US3022012
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User entered 'mmHg'	System	27 Jul 2020 23:31:01

US3022012
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Oct 2020 22:59:52
User entered '83'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User entered 'mmHg'	System	27 Jul 2020 23:31:01

FDA-CBER-2022-1614-0017140

US3022012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11

US3022012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:11

US3022012

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	26 Aug 2020 00:26:33
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	26 Aug 2020 00:26:14
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	21 Aug 2020 00:08:08
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	06 Aug 2020 12:45:24
User entered '27 Jul 2020'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:11

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

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)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

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)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

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)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

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)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

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)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:54:53
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)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

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)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

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)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:54:53
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:54:53
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '0'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '0'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

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)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '0'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:54:53

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)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '0'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

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)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '1'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '0'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:54:53
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '0'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 21:54:53
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:31:53

US3022012

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Sample dated 31AUG2020 is reported under "Unscheduled visit" in PPD Central lab, however the "Immunogenicity Assessment " page under the folder "Unscheduled 31AUG2020" is missing in EDC Please review if the sample has been collected then update the details under appropriate Unscheduled 31AUG2020 visit. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 04:26:35
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Sample dated 31AUG2020 is reported under "Unscheduled visit" in PPD Central lab, however the "Immunogenicity Assessment " page under the folder "Unscheduled 31AUG2020" is missing in EDC Please review if the sample has been collected then update the details under appropriate Unscheduled 31AUG2020 visit. ' answered with 'convalescent visit 28 is 31 aug 2020' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 23:59:19
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Sample dated 31AUG2020 is reported under "Unscheduled visit" in PPD Central lab, however the "Immunogenicity Assessment " page under the folder "Unscheduled 31AUG2020" is missing in EDC Please review if the sample has been collected then update the details under appropriate Unscheduled 31AUG2020 visit. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:47:39
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 31AUG2020 is missing in EDC. Please review if the sample has been collected then update the details under appropriate Unscheduled visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:11:41

US3022012
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Was this visit performed?

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 31AUG2020 is missing in EDC. Please review if the sample has been collected then update the details under appropriate Unscheduled visit. Else clarify, thank you' answered with 'AN UNSCHEUDLED KIT WAS USED FOR THIS VISIT' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:47:13
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 31AUG2020 is missing in EDC. Please review if the sample has been collected then update the details under appropriate Unscheduled visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:24:09
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:32:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '27 Jul 2020'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:32:18

FDA-CBER-2022-1614-0017168

US3022012
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Clinic (Clinic)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:32:18

US3022012
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered 'VISIT1'	System	27 Jul 2020 23:32:18

US3022012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 15:24:33

US3022012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:53

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:01:22
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:01:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Jul 2020 15:24:33
User entered '100005' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 15:24:33

US3022012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:53

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 15:24:33

US3022012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:53

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:27
User closed query 'Complete page' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 13:27:49
Query 'Complete page' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	22 Aug 2020 01:23:40
User entered 'No (N)'	Shanice Bennett (b) (4)	22 Aug 2020 01:23:29
User opened query 'Complete page' (Site from CRA).	(b) (4), (b) (6)	03 Aug 2020 23:42:13

US3022012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:53

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	22 Aug 2020 01:23:29

US3022012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	22 Aug 2020 01:23:29

US3022012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	22 Aug 2020 01:23:29

US3022012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:53

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	22 Aug 2020 01:23:29

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:23:05
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:43:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:43:12
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:26:53
User entered '183.5' cm	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:43:12
User entered '111.4' kg	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:54:53
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:23:05
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:43:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:43:12
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:26:53
User entered '183.5' cm	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:54:53
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:43:12
User entered '111.4' kg	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User accepted default value 'Pre-Dose (PREDOSE)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '27 Jul 2020'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '10:45'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered '27 Jul 2020 10:45'	System	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '98.2' F	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Oral (Oral)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:54:53
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '67'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:54:53
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered 'bpm'	System	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '14'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered 'breaths/min'	System	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '121'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered 'mmHg'	System	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '83'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered 'mmHg'	System	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:23:05
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:43:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:43:12
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:26:53
User entered '183.5' cm	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:54:53
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:43:12
User entered '111.4' kg	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User accepted default value 'Post-Dose (POSTDOSE)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '27 Jul 2020'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Aug 2020 16:14:40
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'CORRECT' (Site from System).	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:40:51
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	27 Jul 2020 23:33:51
User entered '12:57'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered '27 Jul 2020 12:57'	System	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '98.2' F	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Oral (Oral)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '70'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered 'bpm'	System	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '16'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered 'breaths/min'	System	27 Jul 2020 23:33:51

FDA-CBER-2022-1614-0017212

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '110'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered 'mmHg'	System	27 Jul 2020 23:33:51

US3022012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '80'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:33:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered 'mmHg'	System	27 Jul 2020 23:33:51

FDA-CBER-2022-1614-0017216

US3022012
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 21:54:53
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User closed query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 14:16:06
Query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 12:57:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 12:57:44
User opened query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:20:46
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:34:25

US3022012

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 12:57:44
User entered '27 Jul 2020'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:34:25

US3022012
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:54:53
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:56:08

FDA-CBER-2022-1614-0017219

US3022012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:56:08

US3022012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:56:08

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered 'MRNA-1273 OR PLACEBO'	System	27 Jul 2020 16:56:08

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '27 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:56:08

FDA-CBER-2022-1614-0017223

US3022012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '12:09'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:56:08

US3022012
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:54:53

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered '27 Jul 2020 12:09'	System	27 Jul 2020 16:56:08

US3022012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Left Arm (LEFT ARM)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 16:56:08

US3022012
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 21:54:53

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered 'ONCE'	System	27 Jul 2020 16:56:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered 'INTRAMUSCULAR'	System	27 Jul 2020 16:56:08

FDA-CBER-2022-1614-0017228

US3022012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User closed query 'Per IMMUNO Lab Recon: GCL has an Unscheduled sample with date of 31AUG2020; however, there is no record with this date. Please reconcile, make appropriate updates, or else clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:20:51
Query 'Per IMMUNO Lab Recon: GCL has an Unscheduled sample with date of 31AUG2020; however, there is no record with this date. Please reconcile, make appropriate updates, or else clarify.' answered with 'SUBJECT ALSO HAD CONVALESCENT VISIT ON 31AUG2020' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:42:51
User opened query 'Per IMMUNO Lab Recon: GCL has an Unscheduled sample with date of 31AUG2020; however, there is no record with this date. Please reconcile, make appropriate updates, or else clarify.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 09:23:35
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:34:50

US3022012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '27 Jul 2020'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:34:50

US3022012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '11:13'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:34:50

US3022012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered '27 Jul 2020 11:13'	System	27 Jul 2020 23:34:50

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User closed query 'Per SARS-CoV-2 Lab Recon: it appears GCL has a blood sample dated 31AUG2020 as an Unscheduled Visit but it is recorded as V2 D29. Please confirm V2 D29 date of 27AUG2020 is correct. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:41:55
Query 'Per SARS-CoV-2 Lab Recon: it appears GCL has a blood sample dated 31AUG2020 as an Unscheduled Visit but it is recorded as V2 D29. Please confirm V2 D29 date of 27AUG2020 is correct. ' answered with 'SUBJECT ALSO HAD BLOOD SAMPLE ON 31AIG2020 SEE CONVALESCENT VISIT ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:42:19
User opened query 'Per SARS-CoV-2 Lab Recon: it appears GCL has a blood sample dated 31AUG2020 as an Unscheduled Visit but it is recorded as V2 D29. Please confirm V2 D29 date of 27AUG2020 is correct. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:56:49
User entered '27 Jul 2020'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:35:11

US3022012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:53

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:35:11

US3022012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:35:11

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '11:04'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:35:11

US3022012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
Query 'Per GCL Lab Reconciliation: Swab: Sample dated(31AUG2020) is reported under Unscheduled Visit in PPD central lab, however Unscheduled visit with same date is missing in EDC. Please reconcile and confirm the correct visit, else clarify. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 08:27:23
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated(31AUG2020) is reported under Unscheduled Visit in PPD central lab, however Unscheduled visit with same date is missing in EDC. Please reconcile and confirm the correct visit, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 10:44:38
User entered '27 Jul 2020 11:04'	System	27 Jul 2020 23:35:11

US3022012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:53

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:35:11

US3022012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:35:11

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:35:11

US3022012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered empty.	System	27 Jul 2020 23:35:11

US3022012
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	27 Jul 2020 23:35:15

US3022012
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered '1'	System	27 Jul 2020 23:35:15

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:00:51', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '977a1585-39b0-49db-b426-19c178c15425'	System	27 Jul 2020 17:01:08
User entered 'Yes (Y)'	System	27 Jul 2020 17:01:08

US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:00:56', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '977a1585-39b0-49db-b426-19c178c15425'	System	27 Jul 2020 17:01:08
User entered '98.2'	System	27 Jul 2020 17:01:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:01', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '977a1585-39b0-49db-b426-19c178c15425'	System	27 Jul 2020 17:01:08
User entered 'No (N)'	System	27 Jul 2020 17:01:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:05', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '977a1585-39b0-49db-b426-19c178c15425'	System	27 Jul 2020 17:01:08
User entered '27 Jul 2020 13:01'	System	27 Jul 2020 17:01:08

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '27 Jul 2020 12:29'	System	27 Jul 2020 16:56:08

FDA-CBER-2022-1614-0017249

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '27 Jul 2020 14:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 1, after vaccination (at home)'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:19:46', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '687b2c0e-1992-4595-a565-4cb84112ecf5'	System	28 Jul 2020 00:19:56
User entered 'Yes (Y)'	System	28 Jul 2020 00:19:56

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:54:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:19:50', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '687b2c0e-1992-4595-a565-4cb84112ecf5'	System	28 Jul 2020 00:19:56
User entered '98.4'	System	28 Jul 2020 00:19:56

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:19:52', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '687b2c0e-1992-4595-a565-4cb84112ecf5'	System	28 Jul 2020 00:19:56
User entered 'No (N)'	System	28 Jul 2020 00:19:56

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:19:54', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '687b2c0e-1992-4595-a565-4cb84112ecf5'	System	28 Jul 2020 00:19:56
User entered '27 Jul 2020 20:19'	System	28 Jul 2020 00:19:56

US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '27 Jul 2020 15:54'	System	27 Jul 2020 16:56:08

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '28 Jul 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 2'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:04:18', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '271f85c7-5487-4cdc-adb5-7056781c55e2'	System	28 Jul 2020 23:04:36
User entered 'Yes (Y)'	System	28 Jul 2020 23:04:36

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:54:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:04:22', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '271f85c7-5487-4cdc-adb5-7056781c55e2'	System	28 Jul 2020 23:04:36
User entered '101.7'	System	28 Jul 2020 23:04:36

US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:04:25', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '271f85c7-5487-4cdc-adb5-7056781c55e2'	System	28 Jul 2020 23:04:36
User entered 'Yes (Y)'	System	28 Jul 2020 23:04:36

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:54:53
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 17:20:10
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:36:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	28 Jul 2020 23:04:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:04:30', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '271f85c7-5487-4cdc-adb5-7056781c55e2'	System	28 Jul 2020 23:04:36
User entered '1'	System	28 Jul 2020 23:04:36

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:54:53
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:04:30', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '271f85c7-5487-4cdc-adb5-7056781c55e2'	System	28 Jul 2020 23:04:36
User entered '0'	System	28 Jul 2020 23:04:36

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:04:33', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '271f85c7-5487-4cdc-adb5-7056781c55e2'	System	28 Jul 2020 23:04:36
User entered '28 Jul 2020 19:04'	System	28 Jul 2020 23:04:36

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 21:54:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '28 Jul 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '29 Jul 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 3'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:54:53
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:22:48', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '7d1ab8cd-2057-48da-b9d7-79c2ed2a3f29'	System	30 Jul 2020 01:23:09
User entered 'Yes (Y)'	System	30 Jul 2020 01:23:09

US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:22:53', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '7d1ab8cd-2057-48da-b9d7-79c2ed2a3f29'	System	30 Jul 2020 01:23:09
User entered '99.7'	System	30 Jul 2020 01:23:09

US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:53

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '7d1ab8cd-2057-48da-b9d7-79c2ed2a3f29'	System	30 Jul 2020 01:23:09
User entered 'Yes (Y)'	System	30 Jul 2020 01:23:09

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:54:53
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 17:20:15
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:37:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	30 Jul 2020 01:23:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:03', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '7d1ab8cd-2057-48da-b9d7-79c2ed2a3f29'	System	30 Jul 2020 01:23:09
User entered '1'	System	30 Jul 2020 01:23:09

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:54:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:03', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '7d1ab8cd-2057-48da-b9d7-79c2ed2a3f29'	System	30 Jul 2020 01:23:09
User entered '0'	System	30 Jul 2020 01:23:09

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:06', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '7d1ab8cd-2057-48da-b9d7-79c2ed2a3f29'	System	30 Jul 2020 01:23:09
User entered '29 Jul 2020 21:23'	System	30 Jul 2020 01:23:09

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 21:54:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '29 Jul 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '30 Jul 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 4'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T19:59:42', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '120bd97c-29ed-4904-8d03-57b6ef7cdd28'	System	30 Jul 2020 23:59:54
User entered 'Yes (Y)'	System	30 Jul 2020 23:59:54

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:54:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T19:59:45', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '120bd97c-29ed-4904-8d03-57b6ef7cdd28'	System	30 Jul 2020 23:59:54
User entered '99.1'	System	30 Jul 2020 23:59:54

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T19:59:47', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '120bd97c-29ed-4904-8d03-57b6ef7cdd28'	System	30 Jul 2020 23:59:54
User entered 'Yes (Y)'	System	30 Jul 2020 23:59:54

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:54:53
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 17:20:19
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:37:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	30 Jul 2020 23:59:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T19:59:49', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '120bd97c-29ed-4904-8d03-57b6ef7cdd28'	System	30 Jul 2020 23:59:54
User entered '1'	System	30 Jul 2020 23:59:54

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:54:53
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T19:59:49', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '120bd97c-29ed-4904-8d03-57b6ef7cdd28'	System	30 Jul 2020 23:59:54
User entered '0'	System	30 Jul 2020 23:59:54

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T19:59:51', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '120bd97c-29ed-4904-8d03-57b6ef7cdd28'	System	30 Jul 2020 23:59:54
User entered '30 Jul 2020 19:59'	System	30 Jul 2020 23:59:54

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:54:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '30 Jul 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 21:54:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '31 Jul 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 5'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:54:53
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:02:09', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'b11d3c06-bd24-4d1c-9cc9-9f9be37bb69d'	System	01 Aug 2020 10:02:26
User entered 'Yes (Y)'	System	01 Aug 2020 10:02:26

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:54:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:02:14', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'b11d3c06-bd24-4d1c-9cc9-9f9be37bb69d'	System	01 Aug 2020 10:02:26
User entered '98.3'	System	01 Aug 2020 10:02:26

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US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:02:19', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'b11d3c06-bd24-4d1c-9cc9-9f9be37bb69d'	System	01 Aug 2020 10:02:26
User entered 'Yes (Y)'	System	01 Aug 2020 10:02:26

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:54:53
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:02:22', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'b11d3c06-bd24-4d1c-9cc9-9f9be37bb69d'	System	01 Aug 2020 10:02:26
User entered '0'	System	01 Aug 2020 10:02:26

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:54:53
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 17:20:24
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:37:40
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Aug 2020 10:02:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:02:22', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'b11d3c06-bd24-4d1c-9cc9-9f9be37bb69d'	System	01 Aug 2020 10:02:26
User entered '1'	System	01 Aug 2020 10:02:26

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:54:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:02:24', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'b11d3c06-bd24-4d1c-9cc9-9f9be37bb69d'	System	01 Aug 2020 10:02:26
User entered '01 Aug 2020 06:02'	System	01 Aug 2020 10:02:26

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:54:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '31 Jul 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 21:54:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '01 Aug 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 6'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:54:53
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:08:43', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'b2ea656b-ca47-4d50-bc17-654833061480'	System	02 Aug 2020 04:08:55
User entered 'Yes (Y)'	System	02 Aug 2020 04:08:55

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:54:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:08:48', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'b2ea656b-ca47-4d50-bc17-654833061480'	System	02 Aug 2020 04:08:55
User entered '97.8'	System	02 Aug 2020 04:08:55

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:08:50', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'b2ea656b-ca47-4d50-bc17-654833061480'	System	02 Aug 2020 04:08:55
User entered 'No (N)'	System	02 Aug 2020 04:08:55

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:08:52', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'b2ea656b-ca47-4d50-bc17-654833061480'	System	02 Aug 2020 04:08:55
User entered '02 Aug 2020 00:08'	System	02 Aug 2020 04:08:55

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 21:54:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '01 Aug 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '02 Aug 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 7'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:02', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'a7acc9ad-2028-49f2-bf33-4125567b342e'	System	03 Aug 2020 04:48:10
User entered 'Yes (Y)'	System	03 Aug 2020 04:48:10

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:54:53
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:05', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'a7acc9ad-2028-49f2-bf33-4125567b342e'	System	03 Aug 2020 04:48:10
User entered '97.8'	System	03 Aug 2020 04:48:10

US3022012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:07', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'a7acc9ad-2028-49f2-bf33-4125567b342e'	System	03 Aug 2020 04:48:10
User entered 'No (N)'	System	03 Aug 2020 04:48:10

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:08', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'a7acc9ad-2028-49f2-bf33-4125567b342e'	System	03 Aug 2020 04:48:10
User entered '03 Aug 2020 00:48'	System	03 Aug 2020 04:48:10

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:54:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '02 Aug 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 21:54:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '03 Aug 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:54:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:18', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '9fdfae6c-499d-4d8d-aaa9-53e1c4e3e686'	System	27 Jul 2020 17:01:35
User entered 'None (1)'	System	27 Jul 2020 17:01:35

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:25', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '9fdfae6c-499d-4d8d-aaa9-53e1c4e3e686'	System	27 Jul 2020 17:01:35
User entered 'No (N)'	System	27 Jul 2020 17:01:35

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:26', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '9fdfae6c-499d-4d8d-aaa9-53e1c4e3e686'	System	27 Jul 2020 17:01:35
User entered 'No (N)'	System	27 Jul 2020 17:01:35

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:29', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '9fdfae6c-499d-4d8d-aaa9-53e1c4e3e686'	System	27 Jul 2020 17:01:35
User entered 'None (1)'	System	27 Jul 2020 17:01:35

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:31', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '9fdfae6c-499d-4d8d-aaa9-53e1c4e3e686'	System	27 Jul 2020 17:01:35
User entered '27 Jul 2020 13:01'	System	27 Jul 2020 17:01:35

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '27 Jul 2020 12:29'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '27 Jul 2020 14:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 1, after vaccination (at home)'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:20:09', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '18be2bb3-109f-4746-8854-e7ee82c42c6f'	System	28 Jul 2020 00:20:29
User entered 'Does not interfere with activity (2)'	System	28 Jul 2020 00:20:29

FDA-CBER-2022-1614-0017317

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:20:13', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '18be2bb3-109f-4746-8854-e7ee82c42c6f'	System	28 Jul 2020 00:20:29
User entered 'No (N)'	System	28 Jul 2020 00:20:29

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:20:15', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '18be2bb3-109f-4746-8854-e7ee82c42c6f'	System	28 Jul 2020 00:20:29
User entered 'No (N)'	System	28 Jul 2020 00:20:29

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:20:18', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '18be2bb3-109f-4746-8854-e7ee82c42c6f'	System	28 Jul 2020 00:20:29
User entered 'None (1)'	System	28 Jul 2020 00:20:29

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:20:24', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '18be2bb3-109f-4746-8854-e7ee82c42c6f'	System	28 Jul 2020 00:20:29
User entered '27 Jul 2020 20:20'	System	28 Jul 2020 00:20:29

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '27 Jul 2020 15:54'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '28 Jul 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 2'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:04:50', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '80bf70d3-6602-42cc-a5ec-d35d3156cb0d'	System	28 Jul 2020 23:05:12
User entered 'Does not interfere with activity (2)'	System	28 Jul 2020 23:05:12

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:54:53
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:04:52', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '80bf70d3-6602-42cc-a5ec-d35d3156cb0d'	System	28 Jul 2020 23:05:12
User entered 'No (N)'	System	28 Jul 2020 23:05:12

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:05:01', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '80bf70d3-6602-42cc-a5ec-d35d3156cb0d'	System	28 Jul 2020 23:05:12
User entered 'No (N)'	System	28 Jul 2020 23:05:12

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:05:08', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '80bf70d3-6602-42cc-a5ec-d35d3156cb0d'	System	28 Jul 2020 23:05:12
User entered 'None (1)'	System	28 Jul 2020 23:05:12

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:05:11', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '80bf70d3-6602-42cc-a5ec-d35d3156cb0d'	System	28 Jul 2020 23:05:12
User entered '28 Jul 2020 19:05'	System	28 Jul 2020 23:05:12

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:54:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '28 Jul 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 21:54:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '29 Jul 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 3'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:09', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd586add0-d78f-4ea0-b033-972238c3f3fa'	System	30 Jul 2020 01:23:20
User entered 'Does not interfere with activity (2)'	System	30 Jul 2020 01:23:20

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:54:53
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:11', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd586add0-d78f-4ea0-b033-972238c3f3fa'	System	30 Jul 2020 01:23:20
User entered 'No (N)'	System	30 Jul 2020 01:23:20

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:54:53
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:14', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd586add0-d78f-4ea0-b033-972238c3f3fa'	System	30 Jul 2020 01:23:20
User entered 'No (N)'	System	30 Jul 2020 01:23:20

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:16', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd586add0-d78f-4ea0-b033-972238c3f3fa'	System	30 Jul 2020 01:23:20
User entered 'None (1)'	System	30 Jul 2020 01:23:20

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:18', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd586add0-d78f-4ea0-b033-972238c3f3fa'	System	30 Jul 2020 01:23:20
User entered '29 Jul 2020 21:23'	System	30 Jul 2020 01:23:20

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '29 Jul 2020 12:00'	System	27 Jul 2020 16:56:08

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '30 Jul 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 4'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T19:59:55', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '5a38c253-7b2c-4c77-a5cb-9309f730131e'	System	31 Jul 2020 00:00:07
User entered 'None (1)'	System	31 Jul 2020 00:00:07

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:54:53
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T19:59:57', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '5a38c253-7b2c-4c77-a5cb-9309f730131e'	System	31 Jul 2020 00:00:07
User entered 'No (N)'	System	31 Jul 2020 00:00:07

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T19:59:58', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '5a38c253-7b2c-4c77-a5cb-9309f730131e'	System	31 Jul 2020 00:00:07
User entered 'No (N)'	System	31 Jul 2020 00:00:07

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US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T19:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '5a38c253-7b2c-4c77-a5cb-9309f730131e'	System	31 Jul 2020 00:00:07
User entered 'None (1)'	System	31 Jul 2020 00:00:07

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T20:00:03', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '5a38c253-7b2c-4c77-a5cb-9309f730131e'	System	31 Jul 2020 00:00:07
User entered '30 Jul 2020 20:00'	System	31 Jul 2020 00:00:07

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:54:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '30 Jul 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 21:54:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '31 Jul 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 5'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:02:27', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '70b352c5-df1e-4fd2-900d-8c0c58d91483'	System	01 Aug 2020 10:02:37
User entered 'None (1)'	System	01 Aug 2020 10:02:37

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:02:29', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '70b352c5-df1e-4fd2-900d-8c0c58d91483'	System	01 Aug 2020 10:02:37
User entered 'No (N)'	System	01 Aug 2020 10:02:37

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:02:31', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '70b352c5-df1e-4fd2-900d-8c0c58d91483'	System	01 Aug 2020 10:02:37
User entered 'No (N)'	System	01 Aug 2020 10:02:37

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:02:34', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '70b352c5-df1e-4fd2-900d-8c0c58d91483'	System	01 Aug 2020 10:02:37
User entered 'None (1)'	System	01 Aug 2020 10:02:37

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:02:36', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '70b352c5-df1e-4fd2-900d-8c0c58d91483'	System	01 Aug 2020 10:02:37
User entered '01 Aug 2020 06:02'	System	01 Aug 2020 10:02:37

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 21:54:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '31 Jul 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '01 Aug 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 6'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:08:55', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '4af9bc16-e448-40e9-a518-1943162fce94'	System	02 Aug 2020 04:09:06
User entered 'None (1)'	System	02 Aug 2020 04:09:06

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:08:56', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '4af9bc16-e448-40e9-a518-1943162fce94'	System	02 Aug 2020 04:09:06
User entered 'No (N)'	System	02 Aug 2020 04:09:06

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:54:53
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:08:58', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '4af9bc16-e448-40e9-a518-1943162fce94'	System	02 Aug 2020 04:09:06
User entered 'No (N)'	System	02 Aug 2020 04:09:06

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:08:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '4af9bc16-e448-40e9-a518-1943162fce94'	System	02 Aug 2020 04:09:06
User entered 'None (1)'	System	02 Aug 2020 04:09:06

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:09:02', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '4af9bc16-e448-40e9-a518-1943162fce94'	System	02 Aug 2020 04:09:06
User entered '02 Aug 2020 00:09'	System	02 Aug 2020 04:09:06

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:54:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '01 Aug 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 21:54:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '02 Aug 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 7'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:11', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '40f8e61f-c141-4f27-b55d-c33982eede04'	System	03 Aug 2020 04:48:21
User entered 'None (1)'	System	03 Aug 2020 04:48:21

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:54:53
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:13', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '40f8e61f-c141-4f27-b55d-c33982eede04'	System	03 Aug 2020 04:48:21
User entered 'No (N)'	System	03 Aug 2020 04:48:21

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:15', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '40f8e61f-c141-4f27-b55d-c33982eede04'	System	03 Aug 2020 04:48:21
User entered 'No (N)'	System	03 Aug 2020 04:48:21

US3022012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:16', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '40f8e61f-c141-4f27-b55d-c33982eede04'	System	03 Aug 2020 04:48:21
User entered 'None (1)'	System	03 Aug 2020 04:48:21

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:54:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:18', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '40f8e61f-c141-4f27-b55d-c33982eede04'	System	03 Aug 2020 04:48:21
User entered '03 Aug 2020 00:48'	System	03 Aug 2020 04:48:21

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:54:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '02 Aug 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 21:54:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '03 Aug 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:36', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c90079b9-9c50-41fe-9a0b-bdb398c754ee'	System	27 Jul 2020 17:01:51
User entered 'None (0)'	System	27 Jul 2020 17:01:51

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:38', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c90079b9-9c50-41fe-9a0b-bdb398c754ee'	System	27 Jul 2020 17:01:51
User entered 'None (0)'	System	27 Jul 2020 17:01:51

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:39', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c90079b9-9c50-41fe-9a0b-bdb398c754ee'	System	27 Jul 2020 17:01:51
User entered 'None (0)'	System	27 Jul 2020 17:01:51

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:40', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c90079b9-9c50-41fe-9a0b-bdb398c754ee'	System	27 Jul 2020 17:01:51
User entered 'None (0)'	System	27 Jul 2020 17:01:51

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:42', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c90079b9-9c50-41fe-9a0b-bdb398c754ee'	System	27 Jul 2020 17:01:51
User entered 'None (0)'	System	27 Jul 2020 17:01:51

FDA-CBER-2022-1614-0017377

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:43', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c90079b9-9c50-41fe-9a0b-bdb398c754ee'	System	27 Jul 2020 17:01:51
User entered 'None (0)'	System	27 Jul 2020 17:01:51

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:47', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c90079b9-9c50-41fe-9a0b-bdb398c754ee'	System	27 Jul 2020 17:01:51
User entered 'No (N)'	System	27 Jul 2020 17:01:51

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T13:01:49', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c90079b9-9c50-41fe-9a0b-bdb398c754ee'	System	27 Jul 2020 17:01:51
User entered '27 Jul 2020 13:01'	System	27 Jul 2020 17:01:51

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 21:54:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '27 Jul 2020 12:29'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '27 Jul 2020 14:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 1, after vaccination (at home)'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:20:29', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '43a136ea-c6de-4d8a-9528-9a6d4aea8fe1'	System	28 Jul 2020 00:20:46
User entered 'None (0)'	System	28 Jul 2020 00:20:46

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:20:31', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '43a136ea-c6de-4d8a-9528-9a6d4aea8fe1'	System	28 Jul 2020 00:20:46
User entered 'None (0)'	System	28 Jul 2020 00:20:46

FDA-CBER-2022-1614-0017385

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:20:32', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '43a136ea-c6de-4d8a-9528-9a6d4aea8fe1'	System	28 Jul 2020 00:20:46
User entered 'None (0)'	System	28 Jul 2020 00:20:46

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:20:34', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '43a136ea-c6de-4d8a-9528-9a6d4aea8fe1'	System	28 Jul 2020 00:20:46
User entered 'None (0)'	System	28 Jul 2020 00:20:46

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:20:35', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '43a136ea-c6de-4d8a-9528-9a6d4aea8fe1'	System	28 Jul 2020 00:20:46
User entered 'None (0)'	System	28 Jul 2020 00:20:46

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:20:36', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '43a136ea-c6de-4d8a-9528-9a6d4aea8fe1'	System	28 Jul 2020 00:20:46
User entered 'None (0)'	System	28 Jul 2020 00:20:46

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:20:39', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '43a136ea-c6de-4d8a-9528-9a6d4aea8fe1'	System	28 Jul 2020 00:20:46
User entered 'No (N)'	System	28 Jul 2020 00:20:46

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:54:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-27T20:20:40', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '43a136ea-c6de-4d8a-9528-9a6d4aea8fe1'	System	28 Jul 2020 00:20:46
User entered '27 Jul 2020 20:20'	System	28 Jul 2020 00:20:46

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '27 Jul 2020 15:54'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 21:54:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '28 Jul 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 2'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:54:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 13:04:42
Query 'Per DM CLR: Per Diary Dose 1 Day 2 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:51:15
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 08:40:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:05:16', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '2a044aa4-c60f-4df6-b60d-ae97231a5751'	System	28 Jul 2020 23:05:44
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	28 Jul 2020 23:05:44

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:54:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:05:22', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '2a044aa4-c60f-4df6-b60d-ae97231a5751'	System	28 Jul 2020 23:05:44
User entered 'Significant; prevents daily activity (3)'	System	28 Jul 2020 23:05:44

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:54:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:05:26', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '2a044aa4-c60f-4df6-b60d-ae97231a5751'	System	28 Jul 2020 23:05:44
User entered 'Some interference with activity (2)'	System	28 Jul 2020 23:05:44

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:05:29', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '2a044aa4-c60f-4df6-b60d-ae97231a5751'	System	28 Jul 2020 23:05:44
User entered 'None (0)'	System	28 Jul 2020 23:05:44

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:54:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:05:33', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '2a044aa4-c60f-4df6-b60d-ae97231a5751'	System	28 Jul 2020 23:05:44
User entered 'None (0)'	System	28 Jul 2020 23:05:44

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:54:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:05:36', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '2a044aa4-c60f-4df6-b60d-ae97231a5751'	System	28 Jul 2020 23:05:44
User entered 'No interference with activity (1)'	System	28 Jul 2020 23:05:44

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:05:39', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '2a044aa4-c60f-4df6-b60d-ae97231a5751'	System	28 Jul 2020 23:05:44
User entered 'No (N)'	System	28 Jul 2020 23:05:44

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-28T19:05:41', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '2a044aa4-c60f-4df6-b60d-ae97231a5751'	System	28 Jul 2020 23:05:44
User entered '28 Jul 2020 19:05'	System	28 Jul 2020 23:05:44

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 21:54:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '28 Jul 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '29 Jul 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 3'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:54:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:22', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '96ece6e5-8838-4a92-b59e-541f4d555938'	System	30 Jul 2020 01:23:44
User entered 'No interference with activity (1)'	System	30 Jul 2020 01:23:44

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:54:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:24', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '96ece6e5-8838-4a92-b59e-541f4d555938'	System	30 Jul 2020 01:23:44
User entered 'None (0)'	System	30 Jul 2020 01:23:44

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:27', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '96ece6e5-8838-4a92-b59e-541f4d555938'	System	30 Jul 2020 01:23:44
User entered 'None (0)'	System	30 Jul 2020 01:23:44

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:54:53
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:29', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '96ece6e5-8838-4a92-b59e-541f4d555938'	System	30 Jul 2020 01:23:44
User entered 'None (0)'	System	30 Jul 2020 01:23:44

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:54:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:31', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '96ece6e5-8838-4a92-b59e-541f4d555938'	System	30 Jul 2020 01:23:44
User entered 'None (0)'	System	30 Jul 2020 01:23:44

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 21:54:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:33', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '96ece6e5-8838-4a92-b59e-541f4d555938'	System	30 Jul 2020 01:23:44
User entered 'None (0)'	System	30 Jul 2020 01:23:44

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:37', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '96ece6e5-8838-4a92-b59e-541f4d555938'	System	30 Jul 2020 01:23:44
User entered 'No (N)'	System	30 Jul 2020 01:23:44

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-29T21:23:39', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '96ece6e5-8838-4a92-b59e-541f4d555938'	System	30 Jul 2020 01:23:44
User entered '29 Jul 2020 21:23'	System	30 Jul 2020 01:23:44

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '29 Jul 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '30 Jul 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 4'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:54:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T20:00:07', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '8ae95d68-d6b2-4c74-8528-dad82fe3db54'	System	31 Jul 2020 00:00:19
User entered 'No interference with activity (1)'	System	31 Jul 2020 00:00:19

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:54:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T20:00:08', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '8ae95d68-d6b2-4c74-8528-dad82fe3db54'	System	31 Jul 2020 00:00:19
User entered 'None (0)'	System	31 Jul 2020 00:00:19

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T20:00:10', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '8ae95d68-d6b2-4c74-8528-dad82fe3db54'	System	31 Jul 2020 00:00:19
User entered 'None (0)'	System	31 Jul 2020 00:00:19

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:54:53
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T20:00:11', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '8ae95d68-d6b2-4c74-8528-dad82fe3db54'	System	31 Jul 2020 00:00:19
User entered 'None (0)'	System	31 Jul 2020 00:00:19

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T20:00:12', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '8ae95d68-d6b2-4c74-8528-dad82fe3db54'	System	31 Jul 2020 00:00:19
User entered 'None (0)'	System	31 Jul 2020 00:00:19

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:54:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T20:00:13', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '8ae95d68-d6b2-4c74-8528-dad82fe3db54'	System	31 Jul 2020 00:00:19
User entered 'None (0)'	System	31 Jul 2020 00:00:19

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T20:00:15', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '8ae95d68-d6b2-4c74-8528-dad82fe3db54'	System	31 Jul 2020 00:00:19
User entered 'No (N)'	System	31 Jul 2020 00:00:19

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 21:54:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-07-30T20:00:17', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '8ae95d68-d6b2-4c74-8528-dad82fe3db54'	System	31 Jul 2020 00:00:19
User entered '30 Jul 2020 20:00'	System	31 Jul 2020 00:00:19

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '30 Jul 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '31 Jul 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 5'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:54:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:01:47', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f15b8b03-5b79-492f-bee5-6dd939d212d4'	System	01 Aug 2020 10:02:06
User entered 'None (0)'	System	01 Aug 2020 10:02:06

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:54:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:01:50', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f15b8b03-5b79-492f-bee5-6dd939d212d4'	System	01 Aug 2020 10:02:06
User entered 'None (0)'	System	01 Aug 2020 10:02:06

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:54:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:01:52', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f15b8b03-5b79-492f-bee5-6dd939d212d4'	System	01 Aug 2020 10:02:06
User entered 'None (0)'	System	01 Aug 2020 10:02:06

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:54:53
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:01:54', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f15b8b03-5b79-492f-bee5-6dd939d212d4'	System	01 Aug 2020 10:02:06
User entered 'None (0)'	System	01 Aug 2020 10:02:06

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:54:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:01:55', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f15b8b03-5b79-492f-bee5-6dd939d212d4'	System	01 Aug 2020 10:02:06
User entered 'None (0)'	System	01 Aug 2020 10:02:06

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:01:57', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f15b8b03-5b79-492f-bee5-6dd939d212d4'	System	01 Aug 2020 10:02:06
User entered 'None (0)'	System	01 Aug 2020 10:02:06

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:02:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f15b8b03-5b79-492f-bee5-6dd939d212d4'	System	01 Aug 2020 10:02:06
User entered 'No (N)'	System	01 Aug 2020 10:02:06

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-01T06:02:02', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f15b8b03-5b79-492f-bee5-6dd939d212d4'	System	01 Aug 2020 10:02:06
User entered '01 Aug 2020 06:02'	System	01 Aug 2020 10:02:06

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 21:54:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '31 Jul 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '01 Aug 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 6'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:09:04', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd751b61c-91c1-4b0c-a987-b8084513e4b9'	System	02 Aug 2020 04:09:16
User entered 'None (0)'	System	02 Aug 2020 04:09:16

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:54:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:09:05', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd751b61c-91c1-4b0c-a987-b8084513e4b9'	System	02 Aug 2020 04:09:16
User entered 'None (0)'	System	02 Aug 2020 04:09:16

FDA-CBER-2022-1614-0017440

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:54:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:09:08', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd751b61c-91c1-4b0c-a987-b8084513e4b9'	System	02 Aug 2020 04:09:16
User entered 'None (0)'	System	02 Aug 2020 04:09:16

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:54:53
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:09:09', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd751b61c-91c1-4b0c-a987-b8084513e4b9'	System	02 Aug 2020 04:09:16
User entered 'None (0)'	System	02 Aug 2020 04:09:16

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:54:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:09:10', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd751b61c-91c1-4b0c-a987-b8084513e4b9'	System	02 Aug 2020 04:09:16
User entered 'None (0)'	System	02 Aug 2020 04:09:16

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:54:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:09:11', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd751b61c-91c1-4b0c-a987-b8084513e4b9'	System	02 Aug 2020 04:09:16
User entered 'None (0)'	System	02 Aug 2020 04:09:16

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:09:12', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd751b61c-91c1-4b0c-a987-b8084513e4b9'	System	02 Aug 2020 04:09:16
User entered 'No (N)'	System	02 Aug 2020 04:09:16

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-02T00:09:14', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd751b61c-91c1-4b0c-a987-b8084513e4b9'	System	02 Aug 2020 04:09:16
User entered '02 Aug 2020 00:09'	System	02 Aug 2020 04:09:16

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 21:54:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '01 Aug 2020 12:00'	System	27 Jul 2020 16:56:08

US3022012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '02 Aug 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 7'	System	27 Jul 2020 16:56:08

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:54:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:21', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '61cb6a06-4519-449b-a4cf-1c8f62d601ab'	System	03 Aug 2020 04:48:31
User entered 'None (0)'	System	03 Aug 2020 04:48:31

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:54:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:22', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '61cb6a06-4519-449b-a4cf-1c8f62d601ab'	System	03 Aug 2020 04:48:31
User entered 'None (0)'	System	03 Aug 2020 04:48:31

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:54:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:23', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '61cb6a06-4519-449b-a4cf-1c8f62d601ab'	System	03 Aug 2020 04:48:31
User entered 'None (0)'	System	03 Aug 2020 04:48:31

FDA-CBER-2022-1614-0017452

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:54:53
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:24', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '61cb6a06-4519-449b-a4cf-1c8f62d601ab'	System	03 Aug 2020 04:48:31
User entered 'None (0)'	System	03 Aug 2020 04:48:31

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:54:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:25', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '61cb6a06-4519-449b-a4cf-1c8f62d601ab'	System	03 Aug 2020 04:48:31
User entered 'None (0)'	System	03 Aug 2020 04:48:31

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:54:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:26', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '61cb6a06-4519-449b-a4cf-1c8f62d601ab'	System	03 Aug 2020 04:48:31
User entered 'None (0)'	System	03 Aug 2020 04:48:31

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:54:53
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:27', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '61cb6a06-4519-449b-a4cf-1c8f62d601ab'	System	03 Aug 2020 04:48:31
User entered 'No (N)'	System	03 Aug 2020 04:48:31

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:54:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-08-03T00:48:29', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '61cb6a06-4519-449b-a4cf-1c8f62d601ab'	System	03 Aug 2020 04:48:31
User entered '03 Aug 2020 00:48'	System	03 Aug 2020 04:48:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '02 Aug 2020 12:00'	System	27 Jul 2020 16:56:08

FDA-CBER-2022-1614-0017458

US3022012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 21:54:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
User entered '03 Aug 2020 11:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 18:55:19

FDA-CBER-2022-1614-0017460

Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '04 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 18:55:19

US3022012
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 18:55:19

US3022012
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 18:55:19

US3022012
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 18:55:23

US3022012
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered '1'	System	04 Aug 2020 18:55:23

US3022012
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:16:01
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:07

US3022012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '11 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:16:01
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:07

US3022012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:16:01
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:07

US3022012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:07

US3022012

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:19

US3022012
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:48:27
User entered '1'	System	05 Oct 2020 12:10:19

US3022012
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:17:03
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:25

US3022012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:17:03
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:25

US3022012
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:17:03
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:25

US3022012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:17:03
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:25

US3022012
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:17:03
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:31

US3022012
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:17:03
User entered '1'	System	05 Oct 2020 12:10:31

US3022012
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query 2: Previous query response indicates, "convalescent day 28 is completed in edc", however, there is nowhere in the Convalescence Visit Day 28 Folder to add a Swab sample. Please enter the Swab sample data in the COVID-19 Assessments folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:59:54
Query 'Per GCL Lab Reconciliation: Swab: Re-query 2: Previous query response indicates, "convalescent day 28 is completed in edc", however, there is nowhere in the Convalescence Visit Day 28 Folder to add a Swab sample. Please enter the Swab sample data in the COVID-19 Assessments folder, as appropriate.' answered with 'it is entered in COVID-19 assessments folder for 04aug2020' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 19:35:09
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query 2: Previous query response indicates, "convalescent day 28 is completed in edc", however, there is nowhere in the Convalescence Visit Day 28 Folder to add a Swab sample. Please enter the Swab sample data in the COVID-19 Assessments folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 15:19:32
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Previous query response indicates, "31aug2020 is illnes day82", however, this sample is still missing in EDC. Please enter this data in the Covid-19 Assessments folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 15:19:32
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Previous query response indicates, "31aug2020 is illnes day82", however, this sample is still missing in EDC. Please enter this data in the Covid-19 Assessments folder, as appropriate.' answered with 'convalescent day 28 is completed in edc' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 19:19:00

US3022012
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Was this visit performed?

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Previous query response indicates, "31aug2020 is illnes day82", however, this sample is still missing in EDC. Please enter this data in the Covid-19 Assessments folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 16:50:39
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:20:25
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with '31aug2020 is illnes day82' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 14:25:27
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 04:41:47
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:53

US3022012
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:53

US3022012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:53

US3022012
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered 'VISIT2'	System	05 Oct 2020 12:10:53

US3022012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:54:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User accepted default value 'Pre-Dose (PREDOSE)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:54:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:54:53
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:10:59

US3022012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:54:53
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:54:53
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:10:59

US3022012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:54:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User accepted default value 'Post-Dose (POSTDOSE)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

FDA-CBER-2022-1614-0017502

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:54:53
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:54:53
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:10:59

US3022012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:54:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:10:59

FDA-CBER-2022-1614-0017510

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:10:59

US3022012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:54:53
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:10:59

US3022012

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:03

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:03

US3022012
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:54:53
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:08

US3022012
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:54:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User closed query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	05 Oct 2020 12:11:16
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:16
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	05 Oct 2020 12:11:08
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:08

US3022012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:08

US3022012
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:54:53
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:11:08

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:54:53

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:08

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:08

US3022012
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:54:53

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:11:08

US3022012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:08

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:11:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:11:08

FDA-CBER-2022-1614-0017526

US3022012
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 21:54:53
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:20

US3022012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:20

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:20

US3022012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:11:20

US3022012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:54:53

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 31Aug2020 is recorded is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:36:31
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 31Aug2020 is recorded is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' answered with 'visit 2 was skipped' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 18:34:04
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 31Aug2020 is recorded is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 17:55:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:27

US3022012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:53

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:27

US3022012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:27

US3022012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:27

US3022012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:11:27

US3022012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:53

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:27

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:27

FDA-CBER-2022-1614-0017537

US3022012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:27

US3022012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered empty.	System	05 Oct 2020 12:11:27

US3022012
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:11:31

US3022012
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered '1'	System	05 Oct 2020 12:11:31

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:54:13

US3022012
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:54:13

US3022012

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:54:13

US3022012
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:54:13

US3022012
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:54:20

US3022012
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered '1'	System	10 Nov 2020 13:54:20

US3022012
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:54:51

US3022012

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:54:51

US3022012
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:54:51

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:54:51

US3022012
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:55:03
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:54:55

US3022012
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered '1'	System	10 Nov 2020 13:55:03
User entered empty.	System	10 Nov 2020 13:54:55

US3022012
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:55:10

US3022012

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:55:10

US3022012
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:55:10

US3022012

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:55:10

US3022012
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:55:22
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:55:16

US3022012
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered '1'	System	10 Nov 2020 13:55:22
User entered empty.	System	10 Nov 2020 13:55:16

US3022012
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:57:27

US3022012
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '23 Oct 2020'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:57:27

US3022012

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:57:27

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered 'VISIT3'	System	10 Nov 2020 13:57:27

US3022012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:00

US3022012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '23 Oct 2020'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:00

US3022012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '14:29'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:00

US3022012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered '23 Oct 2020 14:29'	System	10 Nov 2020 13:58:00

US3022012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '36.6' C	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:00

US3022012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Oral (Oral)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:00

US3022012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:00

US3022012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '85'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:00

US3022012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered 'bpm'	System	10 Nov 2020 13:58:00

US3022012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '15'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:00

US3022012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered 'breaths/min'	System	10 Nov 2020 13:58:00

US3022012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '135'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:00

US3022012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered 'mmHg'	System	10 Nov 2020 13:58:00

US3022012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '82'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:00

US3022012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered 'mmHg'	System	10 Nov 2020 13:58:00

US3022012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34

US3022012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34

US3022012

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:17

US3022012

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '23 Oct 2020'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:17

US3022012

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:29

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '23 Oct 2020'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:29

FDA-CBER-2022-1614-0017584

US3022012

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '14:35'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:29

US3022012

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered '23 Oct 2020 14:35'	System	10 Nov 2020 13:58:29

US3022012

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 13:58:33

US3022012
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered '1'	System	10 Nov 2020 13:58:33

US3022012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 64'	System	27 Jul 2020 16:56:08

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-09-26T09:58:27', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '6d7ce640-639c-49f4-bd5c-0a7abca8a908'	System	26 Sep 2020 13:58:45
User entered 'No (N)'	System	26 Sep 2020 13:58:45

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-09-26T09:58:32', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '6d7ce640-639c-49f4-bd5c-0a7abca8a908'	System	26 Sep 2020 13:58:45
User entered 'No (N)'	System	26 Sep 2020 13:58:45

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-09-26T09:58:42', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '6d7ce640-639c-49f4-bd5c-0a7abca8a908'	System	26 Sep 2020 13:58:45
User entered '26 Sep 2020 09:58:42'	System	26 Sep 2020 13:58:45

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '26 Sep 2020 00:01'	System	27 Jul 2020 16:56:08

US3022012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '30 Sep 2020 23:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 71'	System	27 Jul 2020 16:56:08

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-10-05T18:53:02', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '1f0b9c88-1c50-4a81-bcaf-7c94d6653efd'	System	05 Oct 2020 22:53:12
User entered 'No (N)'	System	05 Oct 2020 22:53:12

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-10-05T18:53:06', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '1f0b9c88-1c50-4a81-bcaf-7c94d6653efd'	System	05 Oct 2020 22:53:12
User entered 'No (N)'	System	05 Oct 2020 22:53:12

US3022012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-10-05T18:53:08', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '1f0b9c88-1c50-4a81-bcaf-7c94d6653efd'	System	05 Oct 2020 22:53:12
User entered '05 Oct 2020 18:53:08'	System	05 Oct 2020 22:53:12

US3022012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '03 Oct 2020 00:01'	System	27 Jul 2020 16:56:08

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '07 Oct 2020 23:59'	System	27 Jul 2020 16:56:08

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 78'	System	27 Jul 2020 16:56:08

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-10-14T11:59:20', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'fb8aaea0-51ae-480e-857d-b98985bb963d'	System	14 Oct 2020 15:59:28
User entered 'No (N)'	System	14 Oct 2020 15:59:28

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-10-14T11:59:22', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'fb8aaea0-51ae-480e-857d-b98985bb963d'	System	14 Oct 2020 15:59:28
User entered 'No (N)'	System	14 Oct 2020 15:59:28

US3022012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-10-14T11:59:25', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'fb8aaea0-51ae-480e-857d-b98985bb963d'	System	14 Oct 2020 15:59:28
User entered '14 Oct 2020 11:59:25'	System	14 Oct 2020 15:59:28

US3022012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '10 Oct 2020 00:01'	System	27 Jul 2020 16:56:08

US3022012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '14 Oct 2020 23:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 92'	System	27 Jul 2020 16:56:08

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-10-27T14:08:08', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'fc5c091b-291b-4f77-81cd-f30c783df9ec'	System	27 Oct 2020 18:08:14
User entered 'No (N)'	System	27 Oct 2020 18:08:14

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-10-27T14:08:10', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'fc5c091b-291b-4f77-81cd-f30c783df9ec'	System	27 Oct 2020 18:08:14
User entered 'No (N)'	System	27 Oct 2020 18:08:14

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-10-27T14:08:13', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'fc5c091b-291b-4f77-81cd-f30c783df9ec'	System	27 Oct 2020 18:08:14
User entered '27 Oct 2020 14:08:13'	System	27 Oct 2020 18:08:14

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '24 Oct 2020 00:01'	System	27 Jul 2020 16:56:08

US3022012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '28 Oct 2020 23:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 99'	System	27 Jul 2020 16:56:08

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-11-03T17:54:50', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '62aba1cb-d8ff-477f-b3bc-fff43c171fff'	System	03 Nov 2020 22:55:01
User entered 'No (N)'	System	03 Nov 2020 22:55:01

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-11-03T17:54:53', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '62aba1cb-d8ff-477f-b3bc-fff43c171fff'	System	03 Nov 2020 22:55:01
User entered 'No (N)'	System	03 Nov 2020 22:55:01

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-11-03T17:54:58', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '62aba1cb-d8ff-477f-b3bc-fff43c171fff'	System	03 Nov 2020 22:55:01
User entered '03 Nov 2020 17:54:58'	System	03 Nov 2020 22:55:01

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '31 Oct 2020 00:01'	System	27 Jul 2020 16:56:08

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '04 Nov 2020 23:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 106'	System	27 Jul 2020 16:56:08

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-11-11T12:05:43', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c5ff5a18-392e-459e-b322-881bc66e44c7'	System	11 Nov 2020 17:05:52
User entered 'No (N)'	System	11 Nov 2020 17:05:52

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-11-11T12:05:44', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c5ff5a18-392e-459e-b322-881bc66e44c7'	System	11 Nov 2020 17:05:52
User entered 'No (N)'	System	11 Nov 2020 17:05:52

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-11-11T12:05:46', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c5ff5a18-392e-459e-b322-881bc66e44c7'	System	11 Nov 2020 17:05:52
User entered '11 Nov 2020 12:05:46'	System	11 Nov 2020 17:05:52

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '07 Nov 2020 00:01'	System	27 Jul 2020 16:56:08

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '11 Nov 2020 23:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered 'Day 113'	System	27 Jul 2020 16:56:08

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-11-14T00:06:04', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'fae4feea-0f4d-47d7-9f5c-5451dbfac5c6'	System	14 Nov 2020 05:06:13
User entered 'No (N)'	System	14 Nov 2020 05:06:13

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-11-14T00:06:06', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'fae4feea-0f4d-47d7-9f5c-5451dbfac5c6'	System	14 Nov 2020 05:06:13
User entered 'No (N)'	System	14 Nov 2020 05:06:13

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-11-14T00:06:09', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'fae4feea-0f4d-47d7-9f5c-5451dbfac5c6'	System	14 Nov 2020 05:06:13
User entered '14 Nov 2020 00:06:09'	System	14 Nov 2020 05:06:13

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '14 Nov 2020 00:01'	System	27 Jul 2020 16:56:08

US3022012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:30:05
Data entry locked.	System	27 Jul 2020 16:56:08
User entered '18 Nov 2020 23:59'	System	27 Jul 2020 16:56:08

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-12-09T14:03:08', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '206ab732-aa61-4b23-ad91-ddc2f228ab3c'	System	09 Dec 2020 19:03:15
User entered 'No (N)'	System	09 Dec 2020 19:03:15

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-12-09T14:03:09', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '206ab732-aa61-4b23-ad91-ddc2f228ab3c'	System	09 Dec 2020 19:03:15
User entered 'No (N)'	System	09 Dec 2020 19:03:15

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-12-09T14:03:12', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '206ab732-aa61-4b23-ad91-ddc2f228ab3c'	System	09 Dec 2020 19:03:15
User entered '09 Dec 2020 14:03:12'	System	09 Dec 2020 19:03:15

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-12-18T12:00:10', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '3f307f63-f946-4a87-a99a-4f4eff8797b1'	System	18 Dec 2020 18:00:16
User entered 'No (N)'	System	18 Dec 2020 18:00:16

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-12-18T12:00:11', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '3f307f63-f946-4a87-a99a-4f4eff8797b1'	System	18 Dec 2020 18:00:16
User entered 'No (N)'	System	18 Dec 2020 18:00:16

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-12-18T12:00:14', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '3f307f63-f946-4a87-a99a-4f4eff8797b1'	System	18 Dec 2020 18:00:16
User entered '18 Dec 2020 12:00:14'	System	18 Dec 2020 18:00:16

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-12-25T12:14:12', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '935b4d90-6f27-4b25-bb0e-4af23ead53dd'	System	25 Dec 2020 17:14:25
User entered 'No (N)'	System	25 Dec 2020 17:14:25

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-12-25T12:14:17', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '935b4d90-6f27-4b25-bb0e-4af23ead53dd'	System	25 Dec 2020 17:14:25
User entered 'No (N)'	System	25 Dec 2020 17:14:25

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-12-25T12:14:22', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '935b4d90-6f27-4b25-bb0e-4af23ead53dd'	System	25 Dec 2020 17:14:25
User entered '25 Dec 2020 12:14:22'	System	25 Dec 2020 17:14:25

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-12-31T11:47:41', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '3981b777-cb27-4a87-9903-8f7f76e90eb7'	System	31 Dec 2020 16:47:46
User entered 'No (N)'	System	31 Dec 2020 16:47:46

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-12-31T11:47:42', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '3981b777-cb27-4a87-9903-8f7f76e90eb7'	System	31 Dec 2020 16:47:46
User entered 'No (N)'	System	31 Dec 2020 16:47:46

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2020-12-31T11:47:44', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '3981b777-cb27-4a87-9903-8f7f76e90eb7'	System	31 Dec 2020 16:47:46
User entered '31 Dec 2020 11:47:44'	System	31 Dec 2020 16:47:46

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-01-06T00:04:29', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c2b1bc9d-c0be-4e24-a868-6eed2f66cc45'	System	06 Jan 2021 05:04:37
User entered 'No (N)'	System	06 Jan 2021 05:04:37

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-01-06T00:04:31', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c2b1bc9d-c0be-4e24-a868-6eed2f66cc45'	System	06 Jan 2021 05:04:37
User entered 'No (N)'	System	06 Jan 2021 05:04:37

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-01-06T00:04:33', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'c2b1bc9d-c0be-4e24-a868-6eed2f66cc45'	System	06 Jan 2021 05:04:37
User entered '06 Jan 2021 00:04:33'	System	06 Jan 2021 05:04:37

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-01-15T12:36:48', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'edfcb2d5-9a78-4e80-81f7-ad9e55c7dc11'	System	15 Jan 2021 17:37:23
User entered 'No (N)'	System	15 Jan 2021 17:37:23

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-01-15T12:36:49', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'edfcb2d5-9a78-4e80-81f7-ad9e55c7dc11'	System	15 Jan 2021 17:37:23
User entered 'No (N)'	System	15 Jan 2021 17:37:23

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-01-15T12:36:51', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'edfcb2d5-9a78-4e80-81f7-ad9e55c7dc11'	System	15 Jan 2021 17:37:23
User entered '15 Jan 2021 12:36:51'	System	15 Jan 2021 17:37:23

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:02:33

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US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-01-20T15:36:14', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f104c8a2-6530-4d4e-b23d-b42ed4fa6af9'	System	20 Jan 2021 20:36:20
User entered 'No (N)'	System	20 Jan 2021 20:36:20

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-01-20T15:36:15', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f104c8a2-6530-4d4e-b23d-b42ed4fa6af9'	System	20 Jan 2021 20:36:20
User entered 'No (N)'	System	20 Jan 2021 20:36:20

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-01-20T15:36:18', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f104c8a2-6530-4d4e-b23d-b42ed4fa6af9'	System	20 Jan 2021 20:36:20
User entered '20 Jan 2021 15:36:18'	System	20 Jan 2021 20:36:20

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-01-27T16:13:03', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '66082db2-56f3-4999-8040-7c8fa0407111'	System	27 Jan 2021 21:13:11
User entered 'No (N)'	System	27 Jan 2021 21:13:11

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-01-27T16:13:04', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '66082db2-56f3-4999-8040-7c8fa0407111'	System	27 Jan 2021 21:13:11
User entered 'No (N)'	System	27 Jan 2021 21:13:11

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-01-27T16:13:06', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '66082db2-56f3-4999-8040-7c8fa0407111'	System	27 Jan 2021 21:13:11
User entered '27 Jan 2021 16:13:06'	System	27 Jan 2021 21:13:11

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-05T12:01:45', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '58f2901f-6d5f-4da7-af94-4bf65fa75c52'	System	05 Feb 2021 17:06:00
User entered 'No (N)'	System	05 Feb 2021 17:06:00

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-05T12:01:46', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '58f2901f-6d5f-4da7-af94-4bf65fa75c52'	System	05 Feb 2021 17:06:00
User entered 'No (N)'	System	05 Feb 2021 17:06:00

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-05T12:01:49', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '58f2901f-6d5f-4da7-af94-4bf65fa75c52'	System	05 Feb 2021 17:06:00
User entered '05 Feb 2021 12:01:49'	System	05 Feb 2021 17:06:00

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:25', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered 'Yes (Y)'	System	10 Feb 2021 22:00:29

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:29', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered 'No (N)'	System	10 Feb 2021 22:00:29

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:42', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered 'Yes (Y)'	System	10 Feb 2021 22:00:29

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '1'	System	10 Feb 2021 22:00:29

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '1'	System	10 Feb 2021 22:00:29

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Cough

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '0'	System	10 Feb 2021 22:00:29

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Shortness of breath

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '0'	System	10 Feb 2021 22:00:29

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Difficulty breathing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '0'	System	10 Feb 2021 22:00:29

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '1'	System	10 Feb 2021 22:00:29

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Muscle aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '0'	System	10 Feb 2021 22:00:29

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Body aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '1'	System	10 Feb 2021 22:00:29

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Headache

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '1'	System	10 Feb 2021 22:00:29

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

New loss of taste

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '0'	System	10 Feb 2021 22:00:29

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

New loss of smell

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '0'	System	10 Feb 2021 22:00:29

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Sore throat

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '0'	System	10 Feb 2021 22:00:29

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Congestion

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '0'	System	10 Feb 2021 22:00:29

FDA-CBER-2022-1614-0017710

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Runny nose

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '0'	System	10 Feb 2021 22:00:29

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Nausea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '0'	System	10 Feb 2021 22:00:29

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Vomiting

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '0'	System	10 Feb 2021 22:00:29

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Diarrhea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T16:59:59', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '0'	System	10 Feb 2021 22:00:29

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Please 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T17:00:07', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Feb 2021 22:00:29

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T17:00:11', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered 'No (N)'	System	10 Feb 2021 22:00:29

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-10T17:00:13', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '71356bed-389e-4454-a337-acc5b23e3a37'	System	10 Feb 2021 22:00:29
User entered '10 Feb 2021 17:00:13'	System	10 Feb 2021 22:00:29

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-19T12:26:43', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '7f55080b-b3c5-46b3-94e0-6260e33836f1'	System	19 Feb 2021 18:26:49
User entered 'No (N)'	System	19 Feb 2021 18:26:49

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-19T12:26:44', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '7f55080b-b3c5-46b3-94e0-6260e33836f1'	System	19 Feb 2021 18:26:49
User entered 'No (N)'	System	19 Feb 2021 18:26:49

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-19T12:26:47', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '7f55080b-b3c5-46b3-94e0-6260e33836f1'	System	19 Feb 2021 18:26:49
User entered '19 Feb 2021 12:26:47'	System	19 Feb 2021 18:26:49

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:02:33

FDA-CBER-2022-1614-0017726

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-28T12:11:39-05:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f9acb5b7-e1de-44e0-bd03-ea4a69267e78'	System	28 Feb 2021 17:15:17
User entered 'No (N)'	System	28 Feb 2021 17:15:17

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-28T12:11:45-05:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f9acb5b7-e1de-44e0-bd03-ea4a69267e78'	System	28 Feb 2021 17:15:17
User entered 'No (N)'	System	28 Feb 2021 17:15:17

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-28T12:11:47-05:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f9acb5b7-e1de-44e0-bd03-ea4a69267e78'	System	28 Feb 2021 17:15:17
User entered '28 Feb 2021 17:11:47'	System	28 Feb 2021 17:15:17

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-03T04:25:35-05:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '8f9e7be1-bdd5-464a-8cb8-1b1436acffde'	System	03 Mar 2021 09:25:42
User entered 'No (N)'	System	03 Mar 2021 09:25:42

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-03T04:25:36-05:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '8f9e7be1-bdd5-464a-8cb8-1b1436acffde'	System	03 Mar 2021 09:25:42
User entered 'No (N)'	System	03 Mar 2021 09:25:42

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-03T04:25:38-05:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '8f9e7be1-bdd5-464a-8cb8-1b1436acffde'	System	03 Mar 2021 09:25:42
User entered '03 Mar 2021 09:25:38'	System	03 Mar 2021 09:25:42

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-11T22:34:18-05:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'e128edde-43ec-4b3b-a7b7-cde3528da73b'	System	12 Mar 2021 03:34:26
User entered 'No (N)'	System	12 Mar 2021 03:34:26

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-11T22:34:20-05:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'e128edde-43ec-4b3b-a7b7-cde3528da73b'	System	12 Mar 2021 03:34:26
User entered 'No (N)'	System	12 Mar 2021 03:34:26

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-11T22:34:22-05:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'e128edde-43ec-4b3b-a7b7-cde3528da73b'	System	12 Mar 2021 03:34:26
User entered '11 Mar 2021 22:34:22'	System	12 Mar 2021 03:34:26

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:02:33

FDA-CBER-2022-1614-0017744

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-17T12:44:21-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f07db10f-e335-4025-afcd-782e900952f4'	System	17 Mar 2021 16:44:30
User entered 'No (N)'	System	17 Mar 2021 16:44:30

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-17T12:44:25-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f07db10f-e335-4025-afcd-782e900952f4'	System	17 Mar 2021 16:44:30
User entered 'No (N)'	System	17 Mar 2021 16:44:30

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-17T12:44:28-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'f07db10f-e335-4025-afcd-782e900952f4'	System	17 Mar 2021 16:44:30
User entered '17 Mar 2021 12:44:28'	System	17 Mar 2021 16:44:30

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 02:02:33

FDA-CBER-2022-1614-0017749

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-27T15:34:28-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '7bc85d90-0bf6-4daf-9834-03d7b8de12aa'	System	27 Mar 2021 19:34:38
User entered 'No (N)'	System	27 Mar 2021 19:34:38

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-27T15:34:30-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '7bc85d90-0bf6-4daf-9834-03d7b8de12aa'	System	27 Mar 2021 19:34:38
User entered 'No (N)'	System	27 Mar 2021 19:34:38

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-27T15:34:32-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '7bc85d90-0bf6-4daf-9834-03d7b8de12aa'	System	27 Mar 2021 19:34:38
User entered '27 Mar 2021 15:34:32'	System	27 Mar 2021 19:34:38

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-31T20:01:12-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'b40278a3-a488-48e7-8a67-1c127db7e2fe'	System	01 Apr 2021 00:01:42
User entered 'No (N)'	System	01 Apr 2021 00:01:42

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-31T20:01:13-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'b40278a3-a488-48e7-8a67-1c127db7e2fe'	System	01 Apr 2021 00:01:42
User entered 'No (N)'	System	01 Apr 2021 00:01:42

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-03-31T20:01:16-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'b40278a3-a488-48e7-8a67-1c127db7e2fe'	System	01 Apr 2021 00:01:42
User entered '31 Mar 2021 20:01:16'	System	01 Apr 2021 00:01:42

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-04-09T17:41:10-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '355c7e76-e2e5-4632-a00f-58756915b7a4'	System	09 Apr 2021 21:41:16
User entered 'No (N)'	System	09 Apr 2021 21:41:16

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-04-09T17:41:11-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '355c7e76-e2e5-4632-a00f-58756915b7a4'	System	09 Apr 2021 21:41:16
User entered 'No (N)'	System	09 Apr 2021 21:41:16

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-04-09T17:41:13-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '355c7e76-e2e5-4632-a00f-58756915b7a4'	System	09 Apr 2021 21:41:16
User entered '09 Apr 2021 17:41:13'	System	09 Apr 2021 21:41:16

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-04-15T12:36:46-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd4c5f8ff-ef66-401d-a7d6-35ac461d2d22'	System	15 Apr 2021 16:36:54
User entered 'No (N)'	System	15 Apr 2021 16:36:54

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-04-15T12:36:48-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd4c5f8ff-ef66-401d-a7d6-35ac461d2d22'	System	15 Apr 2021 16:36:54
User entered 'No (N)'	System	15 Apr 2021 16:36:54

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-04-15T12:36:50-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: 'd4c5f8ff-ef66-401d-a7d6-35ac461d2d22'	System	15 Apr 2021 16:36:54
User entered '15 Apr 2021 12:36:50'	System	15 Apr 2021 16:36:54

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-04-21T16:55:41-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '9cd9f8f2-bbff-4bc5-b4bc-a1a7a140ece4'	System	21 Apr 2021 20:55:49
User entered 'No (N)'	System	21 Apr 2021 20:55:49

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-04-21T16:55:42-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '9cd9f8f2-bbff-4bc5-b4bc-a1a7a140ece4'	System	21 Apr 2021 20:55:49
User entered 'No (N)'	System	21 Apr 2021 20:55:49

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-04-21T16:55:44-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '9cd9f8f2-bbff-4bc5-b4bc-a1a7a140ece4'	System	21 Apr 2021 20:55:49
User entered '21 Apr 2021 16:55:44'	System	21 Apr 2021 20:55:49

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-04-29T12:03:02-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '201d8048-2d7b-4c6c-8d0f-9c5050d4a664'	System	29 Apr 2021 16:07:54
User entered 'No (N)'	System	29 Apr 2021 16:07:54

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Have you been exposed to someone with 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 (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-04-29T12:03:03-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '201d8048-2d7b-4c6c-8d0f-9c5050d4a664'	System	29 Apr 2021 16:07:54
User entered 'No (N)'	System	29 Apr 2021 16:07:54

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-04-29T12:03:05-04:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '201d8048-2d7b-4c6c-8d0f-9c5050d4a664'	System	29 Apr 2021 16:07:54
User entered '29 Apr 2021 12:03:05'	System	29 Apr 2021 16:07:54

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 02:02:33

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US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:02:33

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US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:02:33

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US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:02:33

FDA-CBER-2022-1614-0017831

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 02:02:33

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 02:02:33

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:02:33

FDA-CBER-2022-1614-0017870

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:02:33

FDA-CBER-2022-1614-0017879

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 02:02:33

FDA-CBER-2022-1614-0017881

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 02:02:33

FDA-CBER-2022-1614-0017890

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:02:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:02:33

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US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:02:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 02:02:33

FDA-CBER-2022-1614-0017925

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 02:02:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:02:33

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US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:02:33

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US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 02:02:33

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US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 02:02:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:02:33

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US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 02:02:33

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:02:33

FDA-CBER-2022-1614-0018002

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 02:02:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 02:02:33

FDA-CBER-2022-1614-0018004

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 02:02:33

US3022012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 21:54:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:33
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 02:02:33

US3022012

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:54:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:49:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-28T12:11:52-05:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '956d35ad-ac47-4a5e-a2e0-f47d1fe93c0f'	System	28 Feb 2021 17:15:17
User entered 'No (N)'	System	28 Feb 2021 17:15:17

US3022012

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:54:53

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:49:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4A5FDE5-6726-40A3-A45C-7AD88A8347D8)', Time: '2021-02-28T12:11:55-05:00', User OID: 'PatientReportedOutcome (US3022012)', ODM File OID: '956d35ad-ac47-4a5e-a2e0-f47d1fe93c0f'	System	28 Feb 2021 17:15:17
User entered '28 Feb 2021 17:11:55'	System	28 Feb 2021 17:15:17

US3022012

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:11:24

US3022012

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User closed query 'Per CDM: Visits Safety Call Day 85 and Safety Call Day 119 are both dated 19NOV2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 04:41:05
Query 'Per CDM: Visits Safety Call Day 85 and Safety Call Day 119 are both dated 19NOV2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:34:46
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 14:34:30
User entered '22 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:34:30
User opened query 'Per CDM: Visits Safety Call Day 85 and Safety Call Day 119 are both dated 19NOV2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 21:12:26
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered '19 Nov 2020'	(b) (4), (b) (6)	07 Dec 2020 14:11:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Dec 2020 14:11:24

FDA-CBER-2022-1614-0018012

US3022012

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:27
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 14:11:24

US3022012
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:11:30

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:15:34
User entered '1'	System	07 Dec 2020 14:11:30

US3022012
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:42:46

US3022012
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '19 Nov 2020'	(b) (4), (b) (6)	29 Dec 2020 18:42:46

US3022012

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:42:46

US3022012

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:42:46

US3022012

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:42:51

US3022012
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User entered '1'	System	29 Dec 2020 18:42:51

US3022012

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:43:01

US3022012
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 31AUG2020 under Unscheduled in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 09:58:49
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 31AUG2020 under Unscheduled in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' answered with 'Convalescent is done with that date' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 19:17:27
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 31AUG2020 under Unscheduled in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:33:25
User entered '24 Dec 2020'	(b) (4), (b) (6)	29 Dec 2020 18:43:01

US3022012
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Dec 2020 18:43:01

US3022012
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:43:01

US3022012

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:43:09

US3022012
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User entered '1'	System	29 Dec 2020 18:43:09

US3022012
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User closed query 'Per GCL Lab Recon: LB 4 Immuno : Sample dated "09 FEB 2021" with sample bar code# 1F621447329 is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in Visit 4 D 209 under Immungenicity assessment form in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 01:33:28
Query 'Per GCL Lab Recon: LB 4 Immuno : Sample dated "09 FEB 2021" with sample bar code# 1F621447329 is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in Visit 4 D 209 under Immungenicity assessment form in EDC. Thank you.' answered with 'updted' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 17:45:55
User opened query 'Per GCL Lab Recon: LB 4 Immuno : Sample dated "09 FEB 2021" with sample bar code# 1F621447329 is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in Visit 4 D 209 under Immungenicity assessment form in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 13:33:15
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Jan 2021 15:51:07

US3022012
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Sample Collection date is recorded as 31AUG2020 under Unscheduled in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 05:38:13
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Sample Collection date is recorded as 31AUG2020 under Unscheduled in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' answered with '31aug2020 was convalescent day 28 which is recorded in EDC under the correct CRF' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 14:28:23
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Sample Collection date is recorded as 31AUG2020 under Unscheduled in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:20:10
User entered '21 Jan 2021'	(b) (4), (b) (6)	21 Jan 2021 15:51:07

FDA-CBER-2022-1614-0018029

US3022012
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Jan 2021 15:51:07

US3022012

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:51:07

US3022012
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is reported under UNSCHEDULED visit in PPD portal; however, data is missing in EDC. Kindly consider updating for the corresponding date (31AUG2020) and updating Immuno sample data under appropriate visit. Else clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:37:42
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is reported under UNSCHEDULED visit in PPD portal; however, data is missing in EDC. Kindly consider updating for the corresponding date (31AUG2020) and updating Immuno sample data under appropriate visit. Else clarify, Thank you.' answered with 'this is already in edc' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:35:20
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is reported under UNSCHEDULED visit in PPD portal; however, data is missing in EDC. Kindly consider updating for the corresponding date (31AUG2020) and updating Immuno sample data under appropriate visit. Else clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 06:29:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Jan 2021 15:51:20

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:45:44
User entered '1'	System	21 Jan 2021 15:51:20

FDA-CBER-2022-1614-0018033

US3022012
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D1 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Vital sign if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 06:52:08
Query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D1 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Vital sign if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately.' answered with 'updated' (Site from DM).	Chevon Roberts (b) (4) (b) (4)	08 Apr 2021 16:50:32
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D1 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Vital sign if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 18:52:21
User closed query 'Per CDM: Visit 4 Day 209 and Participants Decision visit/OL-D1 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on Participants Decision visit/OL D-1 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 18:51:14
Query 'Per CDM: Visit 4 Day 209 and Participants Decision visit/OL-D1 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on Participants Decision visit/OL D-1 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' answered with 'No required per protocol.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 14:01:32

US3022012

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

Was this visit performed?

Audit	User	Time (GMT)
User opened query 'Per CDM: Visit 4 Day 209 and Participants Decision visit/OL-D1 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on Participants Decision visit/OL D-1 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 20:03:51
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	25 Mar 2021 22:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 17:42:41

US3022012
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
	(b) (4)	
User entered '09 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 17:42:41

US3022012

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:42:41

US3022012
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User entered 'VISIT4'	System	10 Mar 2021 17:42:41

US3022012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4)	08 Apr 2021 16:51:40
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	30 Mar 2021 16:08:57

US3022012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered '09 Feb 2021' reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4)	08 Apr 2021 16:51:40
User entered empty.	Chevon Roberts (b) (4) (b) (4)	30 Mar 2021 16:08:57

US3022012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered '15:16' reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4)	08 Apr 2021 16:51:40
User entered empty.	Chevon Roberts (b) (4) (b) (4)	30 Mar 2021 16:08:57

US3022012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User entered '09 Feb 2021 15:16'	System	08 Apr 2021 16:51:40
User entered empty.	System	30 Mar 2021 16:08:57

US3022012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered '36.9' C reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4)	08 Apr 2021 16:51:40
User entered empty.	Chevon Roberts (b) (4) (b) (4)	30 Mar 2021 16:08:57

US3022012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Apr 2021 16:51:46
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	08 Apr 2021 16:51:46
User entered 'Oral (Oral)' reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4)	08 Apr 2021 16:51:46
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Apr 2021 16:51:40
User entered empty.	Chevon Roberts (b) (4) (b) (4)	30 Mar 2021 16:08:57

US3022012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered empty.	Chevon Roberts (b) (4) (b) (4)	30 Mar 2021 16:08:57

US3022012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered '95' reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4)	08 Apr 2021 16:51:40
User entered empty.	Chevon Roberts (b) (4) (b) (4)	30 Mar 2021 16:08:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User entered 'bpm'	System	08 Apr 2021 16:51:40
User entered empty.	System	30 Mar 2021 16:08:57

US3022012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered '15' reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4)	08 Apr 2021 16:51:40
User entered empty.	Chevon Roberts (b) (4) (b) (4)	30 Mar 2021 16:08:57

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User entered 'breaths/min'	System	08 Apr 2021 16:51:40
User entered empty.	System	30 Mar 2021 16:08:57

US3022012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered '129' reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4)	08 Apr 2021 16:51:40
User entered empty.	Chevon Roberts (b) (4) (b) (4)	30 Mar 2021 16:08:57

US3022012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User entered 'mmHg'	System	08 Apr 2021 16:51:40
User entered empty.	System	30 Mar 2021 16:08:57

US3022012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered '84' reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4)	08 Apr 2021 16:51:40
User entered empty.	Chevon Roberts (b) (4) (b) (4)	30 Mar 2021 16:08:57

FDA-CBER-2022-1614-0018052

US3022012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User entered 'mmHg'	System	08 Apr 2021 16:51:40
User entered empty.	System	30 Mar 2021 16:08:57

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30

US3022012

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 17:43:11

Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 21:54:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered '09 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 17:43:11

FDA-CBER-2022-1614-0018057

US3022012

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 17:42:57

US3022012

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered '09 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 17:42:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered '14:44'	(b) (4), (b) (6)	10 Mar 2021 17:42:57

FDA-CBER-2022-1614-0018060

US3022012

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User entered '09 Feb 2021 14:44'	System	10 Mar 2021 17:42:57

US3022012

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 17:43:16

Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:30
User entered '1'	System	10 Mar 2021 17:43:16

US3022012
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 12:50:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 12:50:39

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Mar 2021 12:50:39

FDA-CBER-2022-1614-0018066

US3022012

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 12:50:39

US3022012

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 12:50:43

FDA-CBER-2022-1614-0018068

US3022012
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered '1'	System	29 Mar 2021 12:50:43

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:53

Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:36:16
	(b) (4), (b) (6)	
User entered '03 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 15:06:27
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 15:05:58
Signature has been broken.	(b) (4), (b) (6)	18 Mar 2021 15:05:58
User entered '04 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 15:05:58
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:24:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per CDM, re-query: Please note that per the CRA query contact was made on 03 Aug. Please review source document and verify the date of contact. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 07:34:11
Query 'Per CDM, re-query: Please note that per the CRA query contact was made on 03 Aug. Please review source document and verify the date of contact. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 20:57:22
User entered '03 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 20:57:17
User opened query 'Per CDM, re-query: Please note that per the CRA query contact was made on 03 Aug. Please review source document and verify the date of contact. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 13:41:46

Date of Contact

Audit	User	Time (GMT)
User closed query 'Per CDM, re-query: Please note that per the CRA query contact was made on 03 Aug. Please review source document and verify Date of contact and the date of Day 1 of Symptom log. Please also note that Day 1 of the Symptom log should be the first day the subject has experienced symptoms and it is unusual for it to be after the contact date. Kindly review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:17:59
Query 'Per CDM, re-query: Please note that per the CRA query contact was made on 03 Aug. Please review source document and verify Date of contact and the date of Day 1 of Symptom log. Please also note that Day 1 of the Symptom log should be the first day the subject has experienced symptoms and it is unusual for it to be after the contact date. Kindly review and update as appropriate.' answered with 'this is correct' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 14:23:07
User opened query 'Per CDM, re-query: Please note that per the CRA query contact was made on 03 Aug. Please review source document and verify Date of contact and the date of Day 1 of Symptom log. Please also note that Day 1 of the Symptom log should be the first day the subject has experienced symptoms and it is unusual for it to be after the contact date. Kindly review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 12:24:36
User closed query 'Per CDM: Date of Contact is 03 Aug 2020 and the subject has reported symptoms, yet on the Symptom log Day 1 is recorded for 04 Aug 2020. Please review and update as appropriate to ensure Day 1 on the Symptom log is the first day the subject experienced symptoms, else clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:09:38
Query 'Per CDM: Date of Contact is 03 Aug 2020 and the subject has reported symptoms, yet on the Symptom log Day 1 is recorded for 04 Aug 2020. Please review and update as appropriate to ensure Day 1 on the Symptom log is the first day the subject experienced symptoms, else clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 15:37:00

FDA-CBER-2022-1614-0018071

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:53

Date of Contact

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 15:36:36
User entered '04 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 15:36:36
User opened query 'Per CDM: Date of Contact is 03 Aug 2020 and the subject has reported symptoms, yet on the Symptom log Day 1 is recorded for 04 Aug 2020. Please review and update as appropriate to ensure Day 1 on the Symptom log is the first day the subject experienced symptoms, else clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 13:25:27
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 01:10:42
User closed query 'Per source contact was made 03Aug20. Please confirm with source and update.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:09:38
Query 'Per source contact was made 03Aug20. Please confirm with source and update.' answered with 'UPDATED' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:46:37
User entered '03 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:46:31
User opened query 'Per source contact was made 03Aug20. Please confirm with source and update.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:57:06
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 21:53:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 21:27:32
User entered '04 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:34:11
User entered '06 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:16:06
User entered '05 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:00:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:54:53
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 01:10:41
User closed query 'Per source time of contact is 15:14 on 03Aug20. Please confirm with source and update.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:09:40
Query 'Per source time of contact is 15:14 on 03Aug20. Please confirm with source and update.' answered with 'UPDATED' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:46:44
User entered '15:14' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:46:31
User opened query 'Per source time of contact is 15:14 on 03Aug20. Please confirm with source and update.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:58:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:53:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:27:34
	(b) (4), (b) (6)	
User entered '09:30' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:34:11
User entered '07:32' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:16:06
User entered '13:27'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:00:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:54:53
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '03 Aug 2020 15:14'	System	18 Mar 2021 15:06:27
User entered '04 Aug 2020 15:14'	System	18 Mar 2021 15:05:58
User entered '03 Aug 2020 15:14'	System	06 Jan 2021 20:57:17
User entered '04 Aug 2020 15:14'	System	03 Dec 2020 15:36:36
User entered '03 Aug 2020 15:14'	System	13 Nov 2020 14:46:31
User entered '04 Aug 2020 09:30'	System	03 Nov 2020 21:34:11
User entered '06 Aug 2020 07:32'	System	24 Aug 2020 20:16:06
User entered '05 Aug 2020 13:27'	System	05 Aug 2020 18:00:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:54:53
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 01:10:39
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:53:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:27:35
	(b) (4), (b) (6)	
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:34:11
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:00:32

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:53

Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User closed query 'Per CDM: Site's response is noted. Please request your monitor to unfreeze the required log lines and ensure Day 1 is recorded as the first day the patient has experienced symptoms. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 20:00:01
Query 'Per CDM: Site's response is noted. Please request your monitor to unfreeze the required log lines and ensure Day 1 is recorded as the first day the patient has experienced symptoms. Thank you. ' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 18:16:38
User opened query 'Per CDM: Site's response is noted. Please request your monitor to unfreeze the required log lines and ensure Day 1 is recorded as the first day the patient has experienced symptoms. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:48:41
User closed query 'Per CDM: Please review the start date of Symptoms. Day 1 was recorded for 04 Aug 2020 which is after the contact date and later inactivated. Review and update the Symptom log as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:48:41
Query 'Per CDM: Please review the start date of Symptoms. Day 1 was recorded for 04 Aug 2020 which is after the contact date and later inactivated. Review and update the Symptom log as appropriate. ' answered with 'Please unfreeze so that I can update ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 15:08:09
User opened query 'Per CDM: Please review the start date of Symptoms. Day 1 was recorded for 04 Aug 2020 which is after the contact date and later inactivated. Review and update the Symptom log as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 12:28:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 00:39:04
User closed query 'Please verify as illness visit was completed on 04Aug2020' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 00:39:03
Query 'Please verify as illness visit was completed on 04Aug2020' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	18 Nov 2020 12:44:36

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 21:54:53
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:44:17
User opened query 'Please verify as illness visit was completed on 04Aug2020' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:10:37
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:53:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:27:37
	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:16:06
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:00:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 2 (Day 2)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:53

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Please update symptom day 1 per source subject had a headache on 28,29, and 30 of July. Please update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 03:38:11
User closed query 'Per CDM: It appears initial date (05AUG2020) of symptoms is after the Contact date (04AUG2020). Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 04:29:18
Query 'Please update symptom day 1 per source subject had a headache on 28,29, and 30 of July. Please update accordingly.' answered with 'UPDATED' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:38:18
Query 'Per CDM: It appears initial date (05AUG2020) of symptoms is after the Contact date (04AUG2020). Please reconcile or clarify.' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:38:13
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User opened query 'Please update symptom day 1 per source subject had a headache on 28,29, and 30 of July. Please update accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:46:14
User opened query 'Per CDM: It appears initial date (05AUG2020) of symptoms is after the Contact date (04AUG2020). Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 11:11:00
User entered '05 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '99'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	05 Aug 2020 18:01:20

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.5' F	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:53

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'Mild (Mild)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:53

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	05 Aug 2020 18:01:20
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	05 Aug 2020 18:01:20
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:53

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

FDA-CBER-2022-1614-0018095

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:53

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

FDA-CBER-2022-1614-0018098

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:01:20

FDA-CBER-2022-1614-0018099

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:54:53

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 3 (Day 3)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '06 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '96'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	06 Aug 2020 11:51:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97.9' F	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:54:53

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:54:53

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

FDA-CBER-2022-1614-0018110

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	06 Aug 2020 11:51:57
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:54:53

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	06 Aug 2020 11:51:57
	(b) (4)	

FDA-CBER-2022-1614-0018115

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:54:53

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

FDA-CBER-2022-1614-0018118

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 11:51:57

FDA-CBER-2022-1614-0018120

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	06 Aug 2020 11:51:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 4 (Day 4)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '07 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.7' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:54:53

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:54:53

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:54:53

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:54:53

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:08:37

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:54:53

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 5 (Day 5)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '08 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

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US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:54:53

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:54:53

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
Query 'Per CDM: it appears subject as </= 93% saturation recorded yet it is recorded as NO for O2 Saturation on the Covid Severity Assessment form. Please reconcile or clarify.' canceled (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:54:46
User opened query 'Per CDM: it appears subject as </= 93% saturation recorded yet it is recorded as NO for O2 Saturation on the Covid Severity Assessment form. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:54:18
Query 'Per CDM: it appears subject as </= 93% saturation recorded yet it is recorded as NO for O2 Saturation on the Covid Severity Assessment form. Please reconcile or clarify.' canceled (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:53:53
User opened query 'Per CDM: it appears subject as </= 93% saturation recorded yet it is recorded as NO for O2 Saturation on the Covid Severity Assessment form. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:53:38
User entered '92'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:09:31

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:54:53

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97.3' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:54:53

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:09:31
	(b) (4)	

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:54:53

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:09:31
	(b) (4)	

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

FDA-CBER-2022-1614-0018157

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:09:31
	(b) (4)	

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:54:53

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:09:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 6 (Day 6)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '09 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:11:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '99.3' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:11:57
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:11:57
	(b) (4)	

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US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:54:53

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:54:53

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:11:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:54:53

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:54:53

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:11:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 7 (Day 7)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '10 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:12:54

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:54:53

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97.9' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:54:53

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:54:53

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:12:54

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 8 (Day 8)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '11 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:54:53

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '99'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:13:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.1' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

FDA-CBER-2022-1614-0018219

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:54:53

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:13:40
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:54:53

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:54:53
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

FDA-CBER-2022-1614-0018227

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:54:53

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:13:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 9 (Day 9)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '12 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

FDA-CBER-2022-1614-0018233

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '96'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:15:51

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97.4' F	Shanice Bennett (b) (4)	10 Sep 2020 18:15:51
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

FDA-CBER-2022-1614-0018238

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:54:53

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

FDA-CBER-2022-1614-0018240

Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:15:51
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:15:51

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 10 (Day 10)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '13 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:16:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97.9' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

FDA-CBER-2022-1614-0018260

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:54:53

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:16:49
	(b) (4)	

FDA-CBER-2022-1614-0018262

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:54:53

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:16:49
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:54:53

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

FDA-CBER-2022-1614-0018272

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:16:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 11 (Day 11)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '14 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:17:33

FDA-CBER-2022-1614-0018280

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.3' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:54:53

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

FDA-CBER-2022-1614-0018287

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:54:53

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

FDA-CBER-2022-1614-0018290

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:38:11
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per CDM: Field was left as blank, please complete. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:33:01
Query 'Per CDM: Field was left as blank, please complete. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 15:21:29
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 15:21:22
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 15:21:22
User opened query 'Per CDM: Field was left as blank, please complete. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:25:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:38:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per CDM: Field was left as blank, please complete. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:33:04
Query 'Per CDM: Field was left as blank, please complete. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 15:21:34
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 15:21:22
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 15:21:22
User opened query 'Per CDM: Field was left as blank, please complete. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:25:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:38:15
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per CDM: Field was left as blank, please complete. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:33:06
Query 'Per CDM: Field was left as blank, please complete. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 15:23:09
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 15:21:22
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 15:21:22
User opened query 'Per CDM: Field was left as blank, please complete. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:25:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:17:33

FDA-CBER-2022-1614-0018297

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 12 (Day 12)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '15 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

FDA-CBER-2022-1614-0018299

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:54:53

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.3' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

FDA-CBER-2022-1614-0018312

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

FDA-CBER-2022-1614-0018313

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:18:38
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

FDA-CBER-2022-1614-0018315

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:54:53

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:18:38

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 13 (Day 13)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '16 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '99'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:20:44

FDA-CBER-2022-1614-0018324

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97.7' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:20:44
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:20:44
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:20:44

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 14 (Day 14)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:54:53

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 18:23:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 18:23:34
User entered '17 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 18:21:01
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:54:53

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '99' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:23:34
User entered empty.	System	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.4' F reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:54:53

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:54:53

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4)	10 Sep 2020 18:21:01

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:54:53

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:21:01

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 15 (Day 15)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '18 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97.7' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:54:53

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:23:34
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:54:53

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:23:34
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:23:34

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 16 (Day 16)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:54:53

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '19 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '99'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:24:40

FDA-CBER-2022-1614-0018390

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.2' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:54:53

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

FDA-CBER-2022-1614-0018400

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

FDA-CBER-2022-1614-0018401

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

FDA-CBER-2022-1614-0018402

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:24:40

FDA-CBER-2022-1614-0018407

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 17 (Day 17)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '20 Aug 2020'	Shanice Bennett (b) (4)	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '99'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97.9' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:54:53

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

FDA-CBER-2022-1614-0018417

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

FDA-CBER-2022-1614-0018418

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:54:53

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:54:53

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:25:32

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:54:53

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 18 (Day 18)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '21 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

FDA-CBER-2022-1614-0018431

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:26:33

FDA-CBER-2022-1614-0018434

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.1' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:26:33
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:26:33
	(b) (4)	

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:26:33
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:26:33

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:54:53

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 19 (Day 19)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '22 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97.9' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:27:18
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

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US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:54:53

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:54:53

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:54:53

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:27:18

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 20 (Day 20)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '23 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '99'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:28:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.1' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:54:53

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:54:53

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:28:19
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:28:19
	(b) (4)	

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US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:54:53

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

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US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:54:53

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:28:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 21 (Day 21)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '24 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:54:53

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:29:23

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97.8' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:54:53

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:29:23

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:54:53

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:29:23
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:29:23

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 22 (Day 22)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '25 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

FDA-CBER-2022-1614-0018519

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:30:15

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.1' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

FDA-CBER-2022-1614-0018523

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:54:53

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:30:15

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:54:53

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:30:15

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 23 (Day 23)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '26 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.2' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:31:09

FDA-CBER-2022-1614-0018554

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:54:53

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:09

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 24 (Day 24)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '27 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '99'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:31:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.3' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:31:57

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:54:53

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:54:53

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:31:57
	(b) (4)	

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:54:53

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

FDA-CBER-2022-1614-0018577

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

FDA-CBER-2022-1614-0018578

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

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Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:31:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 25 (Day 25)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '28 Aug 2020'	Shanice Bennett (b) (4)	10 Sep 2020 18:32:57
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:32:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '97.9' F	Shanice Bennett (b) (4)	10 Sep 2020 18:32:57
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:54:53

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:32:57
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

FDA-CBER-2022-1614-0018593

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:39:34
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:46:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:46:01
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

FDA-CBER-2022-1614-0018597

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

FDA-CBER-2022-1614-0018604

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:32:57

FDA-CBER-2022-1614-0018605

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 26 (Day 26)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '29 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:54:53

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.1' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:39:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:46:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:46:01
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:54:53

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:33:49

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:54:53

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per CDM (re-query): Response noted, however Day 28 symptoms are not reported, kindly update else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:29:31
Query 'Per CDM (re-query): Response noted, however Day 28 symptoms are not reported, kindly update else clarify. Thank you.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:17
User opened query 'Per CDM (re-query): Response noted, however Day 28 symptoms are not reported, kindly update else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 04:31:22
User closed query 'Per CDM; Please confirm no Day 28 symptoms reported or make appropriate updates.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 04:31:22
Query 'Per CDM; Please confirm no Day 28 symptoms reported or make appropriate updates.' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:38:38
User opened query 'Per CDM; Please confirm no Day 28 symptoms reported or make appropriate updates.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 11:13:57
User entered 'Day 27 (Day 27)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '30 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '99'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	10 Sep 2020 18:34:35

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:54:53

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered '98.3' F	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Sep 2020 18:34:35
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:39:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:46:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:46:01
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:00:35
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:34:35

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:54:53

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User closed query 'Per CDM: It appears that Day 1 of the symptom log is after the contact date which is unusual. Please review, reconcile and update the symptom log as appropriate, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 19:58:44
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
Query 'Per CDM: It appears that Day 1 of the symptom log is after the contact date which is unusual. Please review, reconcile and update the symptom log as appropriate, else provide clarification. ' answered with 'this is correct patient is unaware when symptoms started' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 18:13:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User opened query 'Per CDM: It appears that Day 1 of the symptom log is after the contact date which is unusual. Please review, reconcile and update the symptom log as appropriate, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 13:17:38
User entered 'Day 1 (Day 1)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 21:54:53
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:03:37
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered '04 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:03:38
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered '0'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:03:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered '96'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 21:54:53
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered '%'	System	13 Nov 2020 14:37:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:03:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered '97.5' F	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:54:53

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:03:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:54:53

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:03:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:54:53

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:03:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:03:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 21:54:53
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:03:52
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:03:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:03:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Nov 2020 14:37:58
	(b) (4)	

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Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:03:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

FDA-CBER-2022-1614-0018663

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:04:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

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New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:04:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012

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Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:04:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:04:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Nov 2020 14:37:58
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:04:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 21:54:53
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:04:11
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:04:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:54:53

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:04:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 18:09:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 19:32:52
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:37:58

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:54:53

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Day 28 (Day 28)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

FDA-CBER-2022-1614-0018672

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:41:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '31 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

FDA-CBER-2022-1614-0018673

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 21:54:53
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:41:52
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User closed query 'Per source, O2 saturation is 98%. Please update.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:03:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:03:23
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
Query 'Per source, O2 saturation is 98%. Please update.' answered with 'updated ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 18:05:44
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 18:05:39
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:05:39
User opened query 'Per source, O2 saturation is 98%. Please update.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:41:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered missing code ND - Not Done.	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User entered '%'	System	18 Nov 2020 12:43:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 21:54:53
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:41:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '97.9' F	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 21:54:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 21:54:53
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:54:53

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 21:54:53

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:54:53

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:11
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:54:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 21:54:53
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:16
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:54:53

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:19
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 21:54:53

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:21
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

FDA-CBER-2022-1614-0018689

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 21:54:53
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:23
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 21:54:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 21:54:53
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:29
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'None (None)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:43:58

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:54:53
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 is present in GCL for an unscheduled visit, please add Swab sample for 31AUG2020 under covid diagnostic test as confirmed under convalescence visit (visit date) query.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:53:36
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 is present in GCL for an unscheduled visit, please add Swab sample for 31AUG2020 under covid diagnostic test as confirmed under convalescence visit (visit date) query.' answered with 'Swab was collected on 31aug2020 instead of saliva sample' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 18:33:19
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 is present in GCL for an unscheduled visit, please add Swab sample for 31AUG2020 under covid diagnostic test as confirmed under convalescence visit (visit date) query.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 08:29:55
User closed query 'Per GCL Lab Recon: it appears GCL has a Swab sample with date of 04AUG2020. Please review and reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:48:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:52
Query 'Per GCL Lab Recon: it appears GCL has a Swab sample with date of 04AUG2020. Please review and reconcile or clarify' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:39:51
User entered '04 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:39:43
User opened query 'Per GCL Lab Recon: it appears GCL has a Swab sample with date of 04AUG2020. Please review and reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:05:22
User entered '05 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:02:14

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:53

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:26:07
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per CDM: Please review this field as it is marked as "No" yet test details are provided. Reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:33:46
Query 'Per CDM: Please review this field as it is marked as "No" yet test details are provided. Reconcile as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:41:19
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 13:41:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 13:41:14
User opened query 'Per CDM: Please review this field as it is marked as "No" yet test details are provided. Reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 13:16:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:52
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:02:14

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:53

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:52
Reviewed for Data Management.	(b) (4), (b) (6)	06 Aug 2020 08:05:58
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)	06 Aug 2020 06:22:24
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 'positive confirmed AE updated' (Site from System).	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:02:45
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	05 Aug 2020 18:02:14
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:02:14

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:54:53
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:26:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per CDM: Please reconcile Date of Test (27JUL2020) and Date of Visit (04AUG2020) or clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:40:13
Query 'Per CDM: Please reconcile Date of Test (27JUL2020) and Date of Visit (04AUG2020) or clarify.' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:36:28
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:36:22
User entered '04 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:36:22
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:52
User opened query 'Per CDM: Please reconcile Date of Test (27JUL2020) and Date of Visit (04AUG2020) or clarify.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 11:12:18
User entered '27 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:02:14

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:54:53
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:52
User entered 'Nasal Swab (Nasal Swab)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	08 Sep 2020 14:22:16
User entered 'Saliva Test (Saliva Test)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	21 Aug 2020 00:04:57
User entered 'Nasal Swab (Nasal Swab)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:02:14

Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:52
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:02:14

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:54:53
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)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:52
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	08 Sep 2020 14:22:12
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	24 Aug 2020 20:16:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:16:51
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	24 Aug 2020 20:16:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:16:37
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 21:54:53

Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:52
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	08 Sep 2020 14:22:12
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 20:16:59
User entered 'ppd' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:16:59
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 20:16:51
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:02:14

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:53

CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:52
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	08 Sep 2020 14:22:12
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	05 Aug 2020 18:02:14

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:53

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
Amendment Manager: User entered '1'	System	21 Aug 2020 01:01:22
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

FDA-CBER-2022-1614-0018704

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 14:24:42
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 14:24:42
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53

Did the subject have Heart Rate $\geq$ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

FDA-CBER-2022-1614-0018708

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 14:24:42
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 14:24:42
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:26:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Per CDM, re-query: Please note that only on Day 5, of the Symptom log (08 Aug) Oxygen Saturation is recorded for ≤ 93% (92%). Please review and update the Start and End Date and Oxygen Saturation recorded below.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:12:21
Query 'Per CDM, re-query: Please note that only on Day 5, of the Symptom log (08 Aug) Oxygen Saturation is recorded for ≤ 93% (92%). Please review and update the Start and End Date and Oxygen Saturation recorded below.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:15:05
User opened query 'Per CDM, re-query: Please note that only on Day 5, of the Symptom log (08 Aug) Oxygen Saturation is recorded for ≤ 93% (92%). Please review and update the Start and End Date and Oxygen Saturation recorded below.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 13:29:26
User closed query 'Per CDM, re-query: Response noted; however in Symptom log Day 5 (08 Aug) O2 Saturation is recorded for 92% and on this page Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?= No. Please reconcile or clarify. If changed to Yes, then please provide start/end date and Oxygen Saturation % in the fields below. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:18:37
Query 'Per CDM, re-query: Response noted; however in Symptom log Day 5 (08 Aug) O2 Saturation is recorded for 92% and on this page Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?= No. Please reconcile or clarify. If changed to Yes, then please provide start/end date and Oxygen Saturation % in the fields below. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 14:24:47
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 14:24:42

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 14:24:42
User opened query 'Per CDM, re-query: Response noted; however in Symptom log Day 5 (08 Aug) O2 Saturation is recorded for 92% and on this page Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?= No. Please reconcile or clarify. If changed to Yes, then please provide start/end date and Oxygen Saturation % in the fields below. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 12:50:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User closed query 'Per CDM: it appears subject as </= 93% saturation recorded in Symptom Log Day 8 yet it is recorded as NO for O2 Saturation on the Covid Severity Assessment form. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:24:40
Query 'Per CDM: it appears subject as </= 93% saturation recorded in Symptom Log Day 8 yet it is recorded as NO for O2 Saturation on the Covid Severity Assessment form. Please reconcile or clarify.' answered with 'THIS IS CORRECT' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:40:28
User opened query 'Per CDM: it appears subject as </= 93% saturation recorded in Symptom Log Day 8 yet it is recorded as NO for O2 Saturation on the Covid Severity Assessment form. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:56:26
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:27:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
	(b) (4)	
User entered '08 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 15:14:59
User entered '10 Aug 2020'	(b) (4), (b) (6)	09 Dec 2020 14:24:42
User closed query 'Per CDM: it appears subject as </= 93% saturation recorded in Symptom Log Day 5 (92%) yet it is recorded as NO for O2 Saturation on the Covid Severity Assessment form. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:10:28
Query 'Per CDM: it appears subject as </= 93% saturation recorded in Symptom Log Day 5 (92%) yet it is recorded as NO for O2 Saturation on the Covid Severity Assessment form. Please reconcile or clarify' answered with 'crf states no' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 15:38:43
User opened query 'Per CDM: it appears subject as </= 93% saturation recorded in Symptom Log Day 5 (92%) yet it is recorded as NO for O2 Saturation on the Covid Severity Assessment form. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 15:22:23
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:26:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Per CDM, re-query: Per Symptom log data Oxygen Saturation is 92% only on 08 Aug and not on the following days. Please review and reconcile with the data recorded on the Symptom log.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 07:21:24
Query 'Per CDM, re-query: Per Symptom log data Oxygen Saturation is 92% only on 08 Aug and not on the following days. Please review and reconcile with the data recorded on the Symptom log.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 19:35:38
User entered '08 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 19:35:32
User opened query 'Per CDM, re-query: Per Symptom log data Oxygen Saturation is 92% only on 08 Aug and not on the following days. Please review and reconcile with the data recorded on the Symptom log.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 12:06:25
User closed query 'Per CDM: Please review and verify the End Date. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 06:28:14
Query 'Per CDM: Please review and verify the End Date. Thank you. ' answered with 'this is end date of oxygen sat that day' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 19:16:53
User opened query 'Per CDM: Please review and verify the End Date. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:12:19
User entered '11 Aug 2020'	(b) (4), (b) (6)	09 Dec 2020 14:24:42
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:27:03
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
User entered '92' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:14:59
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 14:24:42
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 14:24:42
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:54:53

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 14:24:42
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 14:24:42
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
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PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

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US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:27:10
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 19:39:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 19:39:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:39:22
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 19:39:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 19:39:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:39:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:27:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Per CDM re-query: Thank you for the response, however this field is required only if the Did the subject have Respiratory failure? and Did the subject have Acute Respiratory Distress Syndrome (ARDS)? is yes. kindly consider leaving these fields empty. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:43:28
Query 'Per CDM re-query: Thank you for the response, however this field is required only if the Did the subject have Respiratory failure? and Did the subject have Acute Respiratory Distress Syndrome (ARDS)? is yes. kindly consider leaving these fields empty. Otherwise clarify. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 19:39:28
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 19:39:22
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:39:22
User opened query 'Per CDM re-query: Thank you for the response, however this field is required only if the Did the subject have Respiratory failure? and Did the subject have Acute Respiratory Distress Syndrome (ARDS)? is yes. kindly consider leaving these fields empty. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:25:34
User closed query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:21:27

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53

High-Flow Oxygen?

Audit	User	Time (GMT)
Query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly.' answered with 'NO DATA IS ENTERED' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:31:58
User opened query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 21:53:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53

Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:27:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:39:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:39:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:27:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:39:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:39:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:39:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:39:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4)	05 Aug 2020 18:03:40
	(b) (4)	

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	28 Apr 2021 11:14:27
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:04:38
	(b) (4), (b) (6)	
User closed query 'Per CDM: Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg is marked YES, however "start and end date are missing. Please review and reconcile. Else clarify' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 23:34:32
Query 'Per CDM: Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg is marked YES, however "start and end date are missing. Please review and reconcile. Else clarify' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 15:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 15:41:20
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 15:41:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 15:41:20
User opened query 'Per CDM: Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg is marked YES, however "start and end date are missing. Please review and reconcile. Else clarify' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 05:16:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:27:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 19:39:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:39:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:54:53

Evidence of Shock Requires
Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:39:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:39:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4)	05 Aug 2020 18:03:40
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 19:39:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:39:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4)	05 Aug 2020 18:03:40
	(b) (4)	

FDA-CBER-2022-1614-0018744

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4)	05 Aug 2020 18:03:40
	(b) (4)	

US3022012

Folder: Covid-19 Assessment 03 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:54:53

Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 19:39:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:39:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

FDA-CBER-2022-1614-0018747

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53

Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 19:39:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:39:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 19:39:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:39:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4)	05 Aug 2020 18:03:40
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

FDA-CBER-2022-1614-0018754

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:40

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 21:54:53
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:37
User entered empty.	Shanice Bennett (b) (4)	05 Aug 2020 18:03:40
	(b) (4)	

US3022012
Folder: Covid-19 Assessment 03 Aug 2020
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 21:54:53
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:48:02
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:06:44
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	08 Sep 2020 14:21:41
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 18:03:53

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:54:53

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User accepted default value 'Day 3 (Day 3)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:54:53

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:08:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:08:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:08:39
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 12:48:23
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:48:23
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:54:53

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Per GCL Lab Recon: it appears GCL has a Saliva Sample as Unscheduled with date of 31AUG2020. Please review, reconcile if applicable or clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:47:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
Query 'Per GCL Lab Recon: it appears GCL has a Saliva Sample as Unscheduled with date of 31AUG2020. Please review, reconcile if applicable or clarify.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:37:49
User opened query 'Per GCL Lab Recon: it appears GCL has a Saliva Sample as Unscheduled with date of 31AUG2020. Please review, reconcile if applicable or clarify.' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 17:05:49
User entered '06 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:08:39
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:48:23
User entered '06 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:54:53

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User accepted default value 'Day 5 (Day 5)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 21:54:53
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F623187180 is reported with 08AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date for Day 5 in the response and amend the EDC or Preclarus as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:24:59
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F623187180 is reported with 08AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date for Day 5 in the response and amend the EDC or Preclarus as appropriate. Thank you' answered with 'THIS IS CORRECT' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 19:37:29
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F623187180 is reported with 08AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date for Day 5 in the response and amend the EDC or Preclarus as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 11:29:29
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F623187180 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 11:25:30
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F623187180 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'accession number is 1F60019' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:18:20

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:54:53

Was Saliva Collected?

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F623187180 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:16:22
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:08:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:08:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:08:39
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 12:47:56
User entered empty.	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 21:54:53
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:06:38
Query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' answered with 'we have already received these labs' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 17:58:33
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 07:53:21
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, thank you for confirming the Accession number. Please confirm tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 07:53:21
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, thank you for confirming the Accession number. Please confirm tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'this swab is already in PPD lab results' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 18:58:03

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:54:53

Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, thank you for confirming the Accession number. Please confirm tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:07:28
Query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 08AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number to track the sample in PPD. ' canceled (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 04:41:22
User opened query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 08AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 04:41:15
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08,10,12,17,24AUG2020 is recorded under Illness Visit Day 5,7,9,14,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 08:18:48
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08,10,12,17,24AUG2020 is recorded under Illness Visit Day 5,7,9,14,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with '1F617738278' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 14:15:42
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08,10,12,17,24AUG2020 is recorded under Illness Visit Day 5,7,9,14,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:13:46

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:54:53

Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User entered '08 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:08:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:54:53

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User accepted default value 'Day 7 (Day 7)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 21:54:53
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Per GCL LAB reconciliation: Saliva Re-query: PPD reports Day 7 sample with Accession #1F606402602 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date for Day 7 in the response and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:30:32
Query 'Per GCL LAB reconciliation: Saliva Re-query: PPD reports Day 7 sample with Accession #1F606402602 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date for Day 7 in the response and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'THIS DATE IS CORRECT' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 19:37:49
User opened query 'Per GCL LAB reconciliation: Saliva Re-query: PPD reports Day 7 sample with Accession #1F606402602 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date for Day 7 in the response and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 11:30:53
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession #1F606402602 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 11:25:35
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession #1F606402602 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'accession number is 1F60019' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:18:28

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:54:53

Was Saliva Collected?

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession #1F606402602 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:16:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:08:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:08:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:08:39
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 12:47:56
User entered empty.	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:06:31
Query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' answered with 'we have already received these labs' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 17:58:58
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 07:53:30
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response on log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 07:53:30
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response on log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'this swab is already in PPD lab results' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 18:58:10

FDA-CBER-2022-1614-0018770

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:54:53

Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response on log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:07:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User entered '10 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:08:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 21:54:53
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User closed query 'Per GCL LAB reconciliation: Saliva: Please confirm the correct date for DAY9 sample as PPD reports Day 9 (Accession # 1F623110378) with 06AUG2020 and EDC has date as 12Aug2020' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 14:15:21
Query 'Per GCL LAB reconciliation: Saliva: Please confirm the correct date for DAY9 sample as PPD reports Day 9 (Accession # 1F623110378) with 06AUG2020 and EDC has date as 12Aug2020' answered with 'THIS DATE IS CORRECT' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 19:38:02
User opened query 'Per GCL LAB reconciliation: Saliva: Please confirm the correct date for DAY9 sample as PPD reports Day 9 (Accession # 1F623110378) with 06AUG2020 and EDC has date as 12Aug2020' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 05:44:25
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F623110378 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 05:40:23
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F623110378 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'accession number is 1F60019' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:19:20
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F623110378 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:18:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:54:53

Visit

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User accepted default value 'Day 9 (Day 9)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:54:53

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:08:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:08:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:08:39
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 12:47:56
User entered empty.	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:54:53

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:06:27
Query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' answered with 'we have already received these labs' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 17:59:06
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 07:53:37
User closed query ' Per GCL Lab Reconciliation: Saliva: Per previous query response on log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 07:53:37
Query ' Per GCL Lab Reconciliation: Saliva: Per previous query response on log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'this swab is already in PPD lab results' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 18:58:16

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:54:53

Date of Collection

Audit	User	Time (GMT)
User opened query ' Per GCL Lab Reconciliation: Saliva: Per previous query response on log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:08:06
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User entered '12 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:08:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 21:54:53
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621098154 is reported with 06AUG2020 date of Collection. Please "confirm the correct date" for Day 14 and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 05:48:24
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621098154 is reported with 06AUG2020 date of Collection. Please "confirm the correct date" for Day 14 and amend EDC or Preclarus as appropriate. Thank you.' answered with 'this is the correct date' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 15:59:22
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621098154 is reported with 06AUG2020 date of Collection. Please "confirm the correct date" for Day 14 and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 13:03:50
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621098154 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 13:02:43
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621098154 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'accession number is 1F60019' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:18:42

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:54:53

Visit

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621098154 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:18:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User accepted default value 'Day 14 (Day 14)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:54:53

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:08:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:08:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:08:39
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 12:47:56
User entered empty.	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:54:53

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:06:22
Query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' answered with 'we have already received these labs' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 17:59:15
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 07:53:46
User closed query ' Per GCL Lab Reconciliation: Saliva: Per previous query response on log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 07:53:46
Query ' Per GCL Lab Reconciliation: Saliva: Per previous query response on log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'this swab is already in PPD lab results' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 18:58:22

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:54:53

Date of Collection

Audit	User	Time (GMT)
User opened query ' Per GCL Lab Reconciliation: Saliva: Per previous query response on log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:08:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User entered '17 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:08:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

FDA-CBER-2022-1614-0018781

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:54:53

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User accepted default value 'Day 21 (Day 21)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:54:53

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Per GCL LAB reconciliation: Saliva: Please confirm the correct date for DAY9 sample as PPD reports Day 21 (Accession # 1F623650978) with 06AUG2020 and EDC has date as 24Aug2020' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 14:17:26
Query 'Per GCL LAB reconciliation: Saliva: Please confirm the correct date for DAY9 sample as PPD reports Day 21 (Accession # 1F623650978) with 06AUG2020 and EDC has date as 24Aug2020' answered with 'THIS IS CORRECT' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 19:38:16
User opened query 'Per GCL LAB reconciliation: Saliva: Please confirm the correct date for DAY9 sample as PPD reports Day 21 (Accession # 1F623650978) with 06AUG2020 and EDC has date as 24Aug2020' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 11:33:04
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F623650978 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 11:25:55
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F623650978 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'ACCESSION # 1F60019' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:19:05
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F623650978 is reported with 06AUG2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:19:34

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:54:53

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:08:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:08:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:08:39
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 12:47:56
User entered empty.	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:05:30
Query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' answered with 'we have already received these labs' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 17:59:22
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Response confirms about the SWAB sample. however this Saliva sample is missing in PPD. Please review Preclarus and confirm the Accession number and Tracking number for this SALIVA sample as it is missing in PPD' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 07:53:55
User closed query ' Per GCL Lab Reconciliation: Saliva: Per previous query response on log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 07:53:55
Query ' Per GCL Lab Reconciliation: Saliva: Per previous query response on log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'this swab is already in PPD lab results' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 18:58:29

FDA-CBER-2022-1614-0018785

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:54:53

Date of Collection

Audit	User	Time (GMT)
User opened query ' Per GCL Lab Reconciliation: Saliva: Per previous query response on log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:08:30
User closed query 'Per GCL Lab Reconciliation Requery 1:Per response, "Updated", however Saliva sample date 31AUG2020 is still missing in EDC, please verify and update else clarify.Thanks' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:48:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
Query 'Per GCL Lab Reconciliation Requery 1:Per response, "Updated", however Saliva sample date 31AUG2020 is still missing in EDC, please verify and update else clarify.Thanks' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:26:16
User opened query 'Per GCL Lab Reconciliation Requery 1:Per response, "Updated", however Saliva sample date 31AUG2020 is still missing in EDC, please verify and update else clarify.Thanks' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:43:23
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 is reported under Unscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:43:23
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 is reported under Unscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:37:33

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:54:53

Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 is reported under Unscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:15:25
User entered '24 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:08:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:54:53

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User accepted default value 'Day 28 (Day 28)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 21:54:53

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:26:07
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:08:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:08:39
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 17:08:39
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 12:47:56
User entered empty.	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

US3022012

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:54:53

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:53:25
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 05:48:09
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit in the response and update EDC or PPD portal as appropriate. Thank you.' answered with 'YES, AN UNSCHEUDLED KIT WAS USED. ' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:35:45
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 06:05:43
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:09:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:30
User entered '31 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:26:07
User entered empty.	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:56

Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:08
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per GCL Lab Recon: GCL appears to have an Unscheduled Swab, Nasopharyngeal Swab, and SARS_CoV2 samples dated 31AUG2020. Please review and reconcile or clarify ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:40:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:07:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:24
Query 'Per GCL Lab Recon: GCL appears to have an Unscheduled Swab, Nasopharyngeal Swab, and SARS_CoV2 samples dated 31AUG2020. Please review and reconcile or clarify ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:40:48
User opened query 'Per GCL Lab Recon: GCL appears to have an Unscheduled Swab, Nasopharyngeal Swab, and SARS_CoV2 samples dated 31AUG2020. Please review and reconcile or clarify ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 18:55:43
Query 'Per GCL Lab Recon: GCL appears to have an Unscheduled Swab dated 31AUG2020. Please review and reconcile or clarify' canceled (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 18:55:04
User opened query 'Per GCL Lab Recon: GCL appears to have an Unscheduled Swab dated 31AUG2020. Please review and reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 18:54:52
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	21 Aug 2020 00:08:08

US3022012
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:08
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:07:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:24
User closed query 'Per CDM; It appears that both Illness Visit Day 1 and Convalescence Visit Day 28 have the same date of 04AUG2020. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:22:07
Query 'Per CDM; It appears that both Illness Visit Day 1 and Convalescence Visit Day 28 have the same date of 04AUG2020. Please reconcile and update accordingly.' answered with 'CAME IN FOR ILLNESS ON 04AUG2020' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:41:05
User opened query 'Per CDM; It appears that both Illness Visit Day 1 and Convalescence Visit Day 28 have the same date of 04AUG2020. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:02:49
User entered '04 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	21 Aug 2020 00:08:08

US3022012
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

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 19:17:08
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:07:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:24
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4) (b) (4)	21 Aug 2020 00:08:08

US3022012
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:24
User entered 'SICKD1'	System	21 Aug 2020 00:08:08

US3022012
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:09:48

US3022012
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered '04 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:09:48

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US3022012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered '09:56'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:09:48

US3022012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered '04 Aug 2020 09:56'	System	24 Aug 2020 20:09:48

US3022012
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered '97.5' F	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:09:48

US3022012
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered 'Oral (Oral)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:09:48

US3022012
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered empty.	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:09:48

US3022012
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered '73'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:09:48

US3022012
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered 'bpm'	System	24 Aug 2020 20:09:48

US3022012
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered '16'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:09:48

US3022012
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered 'breaths/min'	System	24 Aug 2020 20:09:48

US3022012
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered '124'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:09:48

US3022012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered 'mmHg'	System	24 Aug 2020 20:09:48

US3022012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered '90'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:09:48

FDA-CBER-2022-1614-0018808

US3022012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42
User entered 'mmHg'	System	24 Aug 2020 20:09:48

US3022012
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42

US3022012
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:02:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:42

US3022012

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:15
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:03:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:34
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:12:41

US3022012

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:15
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:03:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:34
User entered '04 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:12:41

US3022012

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:09:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:08:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:41:44
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:12:59

US3022012

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 21:54:53

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:09:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:08:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:41:44
User entered '04 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 20:12:59

FDA-CBER-2022-1614-0018815

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:25
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:09:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:58
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:45:24

US3022012

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:25
User closed query 'Per GCL Lab Reconciliation: Swab: Per response on Convalescence Visit Day 28 (1), "there was no nasal swab collected on 31aug2020. Only labs collected were blood and saliva which are both already logged" & on Covid-19 Assessment 03 Aug 2020 - COVID Diagnostic Test eCRF, "Swab was collected on 31aug2020 instead of saliva sample"; however, per PPD portal, samples for 31-AUG-2020 collected at illness visit for swab samples is present with accession number # 1F600101418 & # 1F623519784 & saliva sample with accession number #1F606919776. Kindly review the accession number, sample name, subject ID & update EDC and Preclarus portal as appropriate, if only saliva sample was collected, if swab was also collected, please initiate Covid -19 Assessment eCRF and update swab data in Covid Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:15:26
Query 'Per GCL Lab Reconciliation: Swab: Per response on Convalescence Visit Day 28 (1), "there was no nasal swab collected on 31aug2020. Only labs collected were blood and saliva which are both already logged" & on Covid-19 Assessment 03 Aug 2020 - COVID Diagnostic Test eCRF, "Swab was collected on 31aug2020 instead of saliva sample"; however, per PPD portal, samples for 31-AUG-2020 collected at illness visit for swab samples is present with accession number # 1F600101418 & # 1F623519784 & saliva sample with accession number #1F606919776. Kindly review the accession number, sample name, subject ID & update EDC and Preclarus portal as appropriate, if only saliva sample was collected, if swab was also collected, please initiate Covid -19 Assessment eCRF and update swab data in Covid Diagnostic Test eCRF, else clarify.' answered with 'swabs were collected for day 28 convalescent. Per lab results current visit is illness day 28. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:02:28

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US3022012

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Per response on Convalescence Visit Day 28 (1), "there was no nasal swab collected on 31aug2020. Only labs collected were blood and saliva which are both already logged" & on Covid-19 Assessment 03 Aug 2020 - COVID Diagnostic Test eCRF, "Swab was collected on 31aug2020 instead of saliva sample"; however, per PPD portal, samples for 31-AUG-2020 collected at illness visit for swab samples is present with accession number # 1F600101418 & # 1F623519784 & saliva sample with accession number #1F606919776. Kindly review the accession number, sample name, subject ID & update EDC and Preclarus portal as appropriate, if only saliva sample was collected, if swab was also collected, please initiate Covid -19 Assessment eCRF and update swab data in Covid Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 03:48:08
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Nasopharyngeal Swab: As we cannot record swab sample under Convalescence Visit form. Please initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 05:33:36
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Nasopharyngeal Swab: As we cannot record swab sample under Convalescence Visit form. Please initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Thank you.' answered with 'there was no nasal swab collected on 31aug2020. Only labs collected were blood and saliva which are both already logged' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 14:29:54
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Nasopharyngeal Swab: As we cannot record swab sample under Convalescence Visit form. Please initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:44:26

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:44:26
Query 'Per GCL Lab Reconciliation: Swab: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form.' answered with 'Covid Contact popped up. Do I put the day of the extra swab?' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 17:23:11
User opened query 'Per GCL Lab Reconciliation: Swab: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 09:34:15
User closed query 'Per GCL Lab reconciliation Re-query: SWAB: Response noted. However, swab sample collected on 31Aug2020 is not yet entered in EDC (Covid Diagnostic Test)' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:59:05
Query 'Per GCL Lab reconciliation Re-query: SWAB: Response noted. However, swab sample collected on 31Aug2020 is not yet entered in EDC (Covid Diagnostic Test)' answered with 'THIS IS ENTERED' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 23:09:57
User opened query 'Per GCL Lab reconciliation Re-query: SWAB: Response noted. However, swab sample collected on 31Aug2020 is not yet entered in EDC (Covid Diagnostic Test)' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:09:45
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 is present in GCL for an unscheduled visit with the same day as this visit, please clarify or reconcile correct date ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:09:45

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 is present in GCL for an unscheduled visit with the same day as this visit, please clarify or reconcile correct date ' answered with 'AN UNSCHEUDLED KIT WAS USED' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:34:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:09:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:58
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 is present in GCL for an unscheduled visit with the same day as this visit, please clarify or reconcile correct date ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:28:06
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:35:58
User entered '04 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:45:24

US3022012

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

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 19:17:25
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:09:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:58
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:45:24

US3022012

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:42:58
User entered 'SICKD28'	System	06 Aug 2020 12:45:24

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:09:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:46:41

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:09:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Oct 2020 17:36:33
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	30 Oct 2020 17:36:33
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:36:33
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Oct 2020 17:35:58
User entered '04 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:46:41

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:09:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered '14:30' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:36:33
User entered '09:56'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:46:41

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered '31 Aug 2020 14:30'	System	30 Oct 2020 17:36:33
User entered '04 Aug 2020 09:56'	System	06 Aug 2020 12:46:41

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:09:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered '97.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:36:33
User entered '97.5' F	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:46:41

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US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:09:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered 'Oral (Oral)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:46:41

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:09:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered empty.	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:46:41

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:09:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered '89' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:36:33
User entered '73'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:46:41

FDA-CBER-2022-1614-0018830

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered 'bpm'	System	06 Aug 2020 12:46:41

US3022012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:09:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:36:33
User entered '16'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:46:41

US3022012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered 'breaths/min'	System	06 Aug 2020 12:46:41

US3022012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:09:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered '122' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:36:33
User entered '124'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:46:41

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered 'mmHg'	System	06 Aug 2020 12:46:41

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:09:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:36:33
User entered '90'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:46:41

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06
User entered 'mmHg'	System	06 Aug 2020 12:46:41

US3022012
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06

US3022012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:11:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:06

US3022012

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:33
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:10:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:21:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:14
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:17

US3022012

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:33
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:10:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:21:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:14
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Oct 2020 17:38:09
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:38:09
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Oct 2020 17:35:58
User entered '04 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:17

FDA-CBER-2022-1614-0018841

US3022012

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:36
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:21:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:21
Query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 04AUG2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under Illness Visit Day 1 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:47:31
User opened query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 04AUG2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under Illness Visit Day 1 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:33:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:39

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:36
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 31 AUG 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 09:12:34
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 31 AUG 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'AN UNSCHEDULE KIT WAS USEDFOR THIS VISIT' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:35:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 16:21:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 21:43:21
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 31 AUG 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:29:09

US3022012

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:54:53

Date of Collection

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 31 AUG 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the UNSCHEDULED visit in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:28:30
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 31 AUG 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the UNSCHEDULED visit in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:28:13
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:37:02
User entered '04 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 12:47:39

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:26:36

FDA-CBER-2022-1614-0018845

US3022012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:26:36

US3022012

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

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Feb 2021 13:26:36

US3022012

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

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered 'UNBLND_DECIDE'	System	10 Feb 2021 13:26:36

US3022012

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:53

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '09 Feb 2021'	(b) (4), (b) (6)	10 Feb 2021 13:29:45

US3022012

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	25 Mar 2021 22:59:02
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:35:04

US3022012

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:53

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 13:29:45

US3022012

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:53

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	25 Mar 2021 22:59:02
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:35:04

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:29:45

FDA-CBER-2022-1614-0018853

US3022012

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:53

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	10 Feb 2021 13:29:45

US3022012

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:53

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User closed query 'Per IRT this subject was received mRNA for Day 1 Dosing. Please update data else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:05:16
Query 'Per IRT this subject was received mRNA for Day 1 Dosing. Please update data else clarify.' answered with 'updated' (Site from DM).	Chevon Roberts (b) (4) (b) (4)	08 Apr 2021 16:49:47
Signature has been broken.	Chevon Roberts (b) (4) (b) (4)	08 Apr 2021 16:49:26
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4)	08 Apr 2021 16:49:26
User opened query 'Per IRT this subject was received mRNA for Day 1 Dosing. Please update data else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 05:32:37
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	10 Feb 2021 13:29:45

US3022012

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:53

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:29:45

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 13:29:45

US3022012

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:53

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered empty.	System	08 Apr 2021 16:49:26
User entered '1'	System	10 Feb 2021 13:29:45

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered '1'	System	10 Feb 2021 13:29:45

US3022012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:54:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:54:53
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:54:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered empty.	System	10 Feb 2021 13:32:41
DataPoint set to visible.	System	10 Feb 2021 13:29:45

US3022012

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:54:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered empty.	System	10 Feb 2021 13:32:41
DataPoint set to visible.	System	10 Feb 2021 13:29:45

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '09 Feb 2021'	(b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '15:16'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered '09 Feb 2021 15:16'	System	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '95'	(b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:54:53
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered 'bpm'	System	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '15'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered 'breaths/min'	System	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '129'	(b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered 'mmHg'	System	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '84'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered 'mmHg'	System	10 Feb 2021 13:32:41

US3022012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:54:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 21:54:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:32:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered empty.	System	10 Feb 2021 13:32:41
DataPoint set to visible.	System	10 Feb 2021 13:29:45

US3022012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 13:32:41

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '16:26'	(b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered '09 Feb 2021 16:26'	System	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '37.0' C	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 13:32:41

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '99'	(b) (4), (b) (6)	10 Feb 2021 13:32:41

FDA-CBER-2022-1614-0018893

US3022012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered 'bpm'	System	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '16'	(b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered 'breaths/min'	System	10 Feb 2021 13:32:41

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '114'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered 'mmHg'	System	10 Feb 2021 13:32:41

US3022012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '82'	(b) (4), (b) (6)	10 Feb 2021 13:32:41

FDA-CBER-2022-1614-0018899

US3022012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered 'mmHg'	System	10 Feb 2021 13:32:41

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 13:29:58

FDA-CBER-2022-1614-0018901

US3022012

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

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:29:58

US3022012

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 13:33:07

US3022012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:54:53
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 13:33:07

US3022012

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

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)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 13:33:07

US3022012

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered 'mRNA-1273'	System	10 Feb 2021 13:33:07
DataPoint set to visible.	System	10 Feb 2021 13:29:45

Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:54:53

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
User entered '09 Feb 2021'	(b) (4), (b) (6)	10 Feb 2021 13:33:07

US3022012

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '15:55'	(b) (4), (b) (6)	10 Feb 2021 13:33:07

US3022012

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered '09 Feb 2021 15:55'	System	10 Feb 2021 13:33:07

US3022012

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Feb 2021 13:33:07

US3022012

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered 'ONCE'	System	10 Feb 2021 13:33:07

US3022012

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

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 13:33:07

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 13:30:37

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '09 Feb 2021'	(b) (4), (b) (6)	10 Feb 2021 13:30:37

FDA-CBER-2022-1614-0018914

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '14:44'	(b) (4), (b) (6)	10 Feb 2021 13:30:37

US3022012

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered '09 Feb 2021 14:44'	System	10 Feb 2021 13:30:37

US3022012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:54:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 13:30:47

US3022012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:54:53

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '09 Feb 2021'	(b) (4), (b) (6)	10 Feb 2021 13:30:47

US3022012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
User entered '14:57'	(b) (4), (b) (6)	10 Feb 2021 13:30:47

US3022012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:54:53

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered '09 Feb 2021 14:57'	System	10 Feb 2021 13:30:47

FDA-CBER-2022-1614-0018920

US3022012

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

Form: Continuing

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 13:30:03

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:29:10
User entered '1'	System	10 Feb 2021 13:30:03

US3022012
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:01
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 13:15:58

US3022012

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:01
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:27
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 13:15:58

US3022012

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:01
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 13:15:58

US3022012
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:01
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 13:15:58

US3022012
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:01
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 13:16:07

US3022012
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:01
User entered '1'	System	17 Feb 2021 13:16:07

US3022012

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:53

OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:01
User entered '1'	System	17 Feb 2021 13:16:07
DataPoint set to visible.	System	17 Feb 2021 13:16:07

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:43:38

US3022012
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dates 09Mar2021 is reported under visit OL-D29: however this is missing in EDC. Please review and update the details under the corresponding visit on the Immunogenicity Assessment form. Thanks. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 02:07:20
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dates 09Mar2021 is reported under visit OL-D29: however this is missing in EDC. Please review and update the details under the corresponding visit on the Immunogenicity Assessment form. Thanks. ' answered with 'labs are not collected at D29' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:48:50
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dates 09Mar2021 is reported under visit OL-D29: however this is missing in EDC. Please review and update the details under the corresponding visit on the Immunogenicity Assessment form. Thanks. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 02:15:28
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09mar2021 is reported under OL-2 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Corresponding Visit on Immunogenicity Assessment page' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:32:09
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09mar2021 is reported under OL-2 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Corresponding Visit on Immunogenicity Assessment page' answered with 'this is correct ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:32:19

US3022012
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09mar2021 is reported under OL-2 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Corresponding Visit on Immunogenicity Assessment page' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:57:58
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	25 Mar 2021 22:59:02
User entered '09 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 17:43:38

US3022012
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53

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 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Mar 2021 17:43:38

US3022012
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered 'OLD29'	System	10 Mar 2021 17:43:38

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered '09 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 17:44:45

FDA-CBER-2022-1614-0018937

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered '15:18'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered '09 Mar 2021 15:18'	System	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
	(b) (4)	
User entered '82'	(b) (4), (b) (6)	10 Mar 2021 17:44:45

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered 'bpm'	System	10 Mar 2021 17:44:45

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered '14'	(b) (4), (b) (6)	10 Mar 2021 17:44:45

FDA-CBER-2022-1614-0018945

US3022012
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 21:54:53
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered 'breaths/min'	System	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered '124'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered 'mmHg'	System	10 Mar 2021 17:44:45

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered '77'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

FDA-CBER-2022-1614-0018949

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered 'mmHg'	System	10 Mar 2021 17:44:45

FDA-CBER-2022-1614-0018950

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered empty.	System	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:54:53

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:44:45

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

FDA-CBER-2022-1614-0018959

US3022012
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:54:53
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered empty.	System	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:54:53
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered empty.	System	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered empty.	System	10 Mar 2021 17:44:45

US3022012
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 21:54:53
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered empty.	System	10 Mar 2021 17:44:45

US3022012

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:56

US3022012

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:44:56

US3022012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:45:59

US3022012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered 'Other (OTHER)'	(b) (4), (b) (6)	30 Mar 2021 17:45:59

US3022012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

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)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered 'subject got dosed at ol visit'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:45:59

US3022012
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:54:53

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
DataPoint set to visible.	System	08 Apr 2021 16:49:26
User entered empty.	System	30 Mar 2021 17:45:59
DataPoint set to invisible.	System	17 Feb 2021 13:16:07

US3022012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:53

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:45:59

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:45:59

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered empty.	System	30 Mar 2021 17:45:59

US3022012
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 21:54:53

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:45:59

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered empty.	System	30 Mar 2021 17:45:59

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What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered empty.	System	30 Mar 2021 17:45:59

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US3022012

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:45:09

US3022012

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:53

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:18
User entered '1'	System	10 Mar 2021 17:45:09

US3022012
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:54:42
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 15:29:34

US3022012
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:54:42
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered '19 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 15:29:34

US3022012
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:54:42
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	31 Mar 2021 15:29:34

US3022012
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 21:54:53
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:54:42
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:29:34

US3022012

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:54:42
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:29:45

US3022012
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 11 Aug 2021 21:54:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:54:42
User entered '1'	System	31 Mar 2021 15:29:45

US3022012

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 19:17:36

US3022012

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
	(b) (4)	
User entered '13 Apr 2021'	(b) (4), (b) (6)	13 Apr 2021 19:17:36

US3022012

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Apr 2021 19:17:36

US3022012
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 21:54:53
Folder OID

Audit	User	Time (GMT)
User entered 'OLD57'	System	13 Apr 2021 19:17:36

US3022012
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:19:32

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered '13 Apr 2021'	(b) (4), (b) (6)	13 Apr 2021 19:19:32

FDA-CBER-2022-1614-0018992

US3022012

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
User entered '14:50'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:19:32

US3022012
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '13 Apr 2021 14:50'	System	13 Apr 2021 19:19:32

US3022012

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered '36.8' C	(b) (4), (b) (6)	13 Apr 2021 19:19:32

US3022012

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Apr 2021 19:19:32

US3022012
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 19:19:32

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
	(b) (4)	
User entered '70'	(b) (4), (b) (6)	13 Apr 2021 19:19:32

FDA-CBER-2022-1614-0018998

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Apr 2021 19:19:32

US3022012
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	13 Apr 2021 19:19:32

US3022012
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Apr 2021 19:19:32

US3022012
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered '105'	(b) (4), (b) (6)	13 Apr 2021 19:19:32

US3022012

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 19:19:32

US3022012
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
	(b) (4)	
User entered '65'	(b) (4), (b) (6)	13 Apr 2021 19:19:32

US3022012
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 21:54:53
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 19:19:32

US3022012

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 19:20:38

US3022012

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
	(b) (4)	
User entered '13 Apr 2021'	(b) (4), (b) (6)	13 Apr 2021 19:20:38

US3022012

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:09:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 19:21:55

US3022012

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
	(b) (4)	
User entered '13 Apr 2021'	(b) (4), (b) (6)	13 Apr 2021 19:21:55

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:09:53
	(b) (4)	
User entered '15:01'	(b) (4), (b) (6)	13 Apr 2021 19:21:55

US3022012

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:53

Collection date and time (derived)

Audit	User	Time (GMT)
User entered '13 Apr 2021 15:01'	System	13 Apr 2021 19:21:55

Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 21:54:53

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:09:57
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per CDM: Please note that the start time of AE#1 (08:00) is prior to Exposure time (12:09). Please review and update as appropriate, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 14:45:33
Query 'Per CDM: Please note that the start time of AE#1 (08:00) is prior to Exposure time (12:09). Please review and update as appropriate, else provide clarification. ' answered with 'this is time tested positive ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:31:15
User opened query 'Per CDM: Please note that the start time of AE#1 (08:00) is prior to Exposure time (12:09). Please review and update as appropriate, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 14:16:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:51
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:01:02

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US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

AEID

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:34:24
User entered 'USA-US051-2020-mRNA-1273-P301000002'	System	28 Aug 2020 17:33:52
User entered 'New'	(b) (4), (b) (6)	28 Aug 2020 17:33:52

US3022012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:54:53
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User closed query 'PV Query: Please consider updating event term to COVID-19, as diagnosis was confirmed by both diagnostic test results and the subject's clinical presentation.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 16:30:25
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)	29 Sep 2020 15:38:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:38:52
Data point term sent to Coder	System	29 Sep 2020 15:37:51
Query 'PV Query: Please consider updating event term to COVID-19, as diagnosis was confirmed by both diagnostic test results and the subject's clinical presentation.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	29 Sep 2020 15:37:32
Coding entries removed.	Shanice Bennett (b) (4) (b) (4)	29 Sep 2020 15:37:26
User entered 'COVID-19' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	29 Sep 2020 15:37:26
User opened query 'PV Query: Please consider updating event term to COVID-19, as diagnosis was confirmed by both diagnostic test results and the subject's clinical presentation.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 12:32:10
User closed query 'Per MM: Please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject will be diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 13:40:28

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

Adverse event

Audit	User	Time (GMT)
Query 'Per MM: Please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject will be diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose ' answered with 'Yes IP withdrawal ' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	18 Sep 2020 12:15:28
User opened query 'Per MM: Please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject will be diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:40:55
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 19:04:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 19:04:03
Data point term sent to Coder	System	04 Aug 2020 19:03:16
User entered 'Positive COVID-19'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

US3022012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:54:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	28 Aug 2020 12:18:24
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	28 Aug 2020 12:18:05
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User closed query 'PV Query: Please report the reason for the delay in reporting the event.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 16:30:31
Query 'PV Query: Please report the reason for the delay in reporting the event.' answered with 'subject was swabbed at baseline this day and test results came back on 02Aug2020' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	29 Sep 2020 15:37:53
User opened query 'PV Query: Please report the reason for the delay in reporting the event.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 12:31:26
User closed query 'PV Query: Please confirm the date of event onset. It is reported that the subject had a positive test on the 27-Jul-2020, but start date is currently reported as 03-Aug-2020.' (Site from Safety).	(b) (4), (b) (6)	12 Sep 2020 17:31:03
Query 'PV Query: Please confirm the date of event onset. It is reported that the subject had a positive test on the 27-Jul-2020, but start date is currently reported as 03-Aug-2020.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:04:53
User entered '27 Jul 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:04:41
User opened query 'PV Query: Please confirm the date of event onset. It is reported that the subject had a positive test on the 27-Jul-2020, but start date is currently reported as 03-Aug-2020.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 14:30:46
User entered '03 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

FDA-CBER-2022-1614-0019019

US3022012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 18:05:22
User entered '08:00' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:05:22
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 18:04:41
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	04 Aug 2020 19:02:55
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:55
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	04 Aug 2020 19:02:46
User entered '08:00'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

AE start date and time (derived)

Audit	User	Time (GMT)
User entered '27 Jul 2020 08:00'	System	10 Sep 2020 18:05:22
User entered empty.	System	04 Aug 2020 19:02:55
User entered '03 Aug 2020 08:00'	System	04 Aug 2020 19:02:46

US3022012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 21:54:53

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	21 Oct 2020 20:59:12
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 22:09:11
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	21 Oct 2020 20:59:35
User entered '15 Sep 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	21 Oct 2020 20:59:12
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 13:05:57
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Sep 2020 17:31:11
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'still open subject tested positive at convalescent visit 2 ' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:05:55
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 14:29:21
User entered empty.	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 11:37:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 01:12:27
User closed query 'Re-query: If source doesn't note time the time should not be entered. As entered it appears to be midnight.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:12:17
Query 'Data is required. Please provide.' answered with 'no time recorded' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 13:52:32
Query 'Re-query: If source doesn't note time the time should not be entered. As entered it appears to be midnight.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 13:52:22
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Nov 2020 13:52:01
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	16 Nov 2020 13:52:01
User opened query 'Re-query: If source doesn't note time the time should not be entered. As entered it appears to be midnight.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:02:17
User closed query 'Please confirm or clarify time as source doesn't note time.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:02:17
Query 'Please confirm or clarify time as source doesn't note time.' answered with 'UPDATED' (Site from CRA).	Morgan Deal (b) (4)	12 Nov 2020 20:17:24
DataPoint Un-verified.	Morgan Deal (b) (4)	12 Nov 2020 20:17:15
User entered '00:00' reason for change: Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 20:17:15
User opened query 'Please confirm or clarify time as source doesn't note time.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:46:17
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 20:59:27
User entered '08:00' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	21 Oct 2020 20:59:27
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 20:59:12
User entered empty.	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 13:52:01
User entered '15 Sep 2020 00:00'	System	12 Nov 2020 20:17:15
User entered '15 Sep 2020 08:00'	System	21 Oct 2020 20:59:27
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 16:30:35
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 14:51:37
User entered empty.	System	04 Aug 2020 19:02:46

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US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

Severity

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User closed query 'PV Query: As event did not meet seriousness criteria, please consider downgrading the intensity from Grade 3.' (Site from Safety).	(b) (4), (b) (6)	12 Sep 2020 17:31:46
Query 'PV Query: As event did not meet seriousness criteria, please consider downgrading the intensity from Grade 3.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:06:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:04:41
User opened query 'PV Query: As event did not meet seriousness criteria, please consider downgrading the intensity from Grade 3.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 14:28:54
User entered 'Grade 3/Severe (Grade 3/Severe)'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered '0'	Shanice Bennett (b) (4)	04 Aug 2020 19:02:46
	(b) (4)	

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered '0'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered '0'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered empty.	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

US3022012
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Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered empty.	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered empty.	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered empty.	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered '0'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Folder: Adverse Events

Form: Adverse Events (1)

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered '0'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Form: Adverse Events (1)

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Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered '0'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Folder: Adverse Events
Form: Adverse Events (1)
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Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 02:07:27
User closed query 'PV Query Urgent: Please confirm the related causality assessment. ' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 12:51:39
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 21:46:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 21:46:31
Query 'PV Query Urgent: Please confirm the related causality assessment. ' answered with 'Per sponsor request' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 21:26:16
User opened query 'PV Query Urgent: Please confirm the related causality assessment. ' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:23:39
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	10 Sep 2020 18:06:22
User entered 'Related (RELATED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:06:22
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	10 Sep 2020 18:04:41
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Folder: Adverse Events
Form: Adverse Events (1)
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Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 13:45:30
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation and End of study eCRF if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:45:02
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'updted' (Site from System).	Shanice Bennett (b) (4) (b) (4)	29 Sep 2020 15:40:33
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	29 Sep 2020 15:39:18
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation and End of study eCRF if applicable. Review and update. Else, clarify. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	29 Sep 2020 15:38:10
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation and End of study eCRF if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:11:19
User closed query 'PV Query: Please confirm action taken as none. Will patient continue in study? If no, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	12 Sep 2020 17:31:55

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: Please confirm action taken as none. Will patient continue in study? If no, please update action taken to withdrawn.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:06:18
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:04:41
User opened query 'PV Query: Please confirm action taken as none. Will patient continue in study? If no, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 14:28:40
User entered 'None (NONE)'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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None

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 01:12:41
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 13:52:12
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 13:52:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered '1'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is HEADACHE/FEVER. Please review if the AE term (COVID-19) should be added as a CM indication so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:27:43
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is HEADACHE/FEVER. Please review if the AE term (COVID-19) should be added as a CM indication so there will be an appropriate match. Otherwise, clarify. ' answered with 'Con med log updated with Tylenol taken 28Jul2020.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 14:10:46
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is HEADACHE/FEVER. Please review if the AE term (COVID-19) should be added as a CM indication so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 00:37:14
User closed query 'Re-query: If taken for this AE as previous query response notes than this field should be checked.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:12:50
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 01:12:43
Query 'Re-query: If taken for this AE as previous query response notes than this field should be checked.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 13:52:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 13:52:12
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 13:52:12
User opened query 'Re-query: If taken for this AE as previous query response notes than this field should be checked.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:03:07
User closed query 'Please confirm Tylenol was taken for Covid symptom. Please update if needed.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:03:07

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Concomitant Medication

Audit	User	Time (GMT)
Query 'Please confirm Tylenol was taken for Covid symptom. Please update if needed.' answered with 'YES IT WAS TAKEN FOR COVID SYMPTOM' (Site from CRA).	Morgan Deal (b) (4)	12 Nov 2020 20:21:43
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User opened query 'Please confirm Tylenol was taken for Covid symptom. Please update if needed.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:41:21
Query 'Please confirm Conmeds taken for AE.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:40:37
User opened query 'Please confirm Conmeds taken for AE.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:39:13
User entered '0'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered '0'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
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)	22 Oct 2020 22:09:18
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 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	21 Oct 2020 20:59:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	21 Oct 2020 20:59:12
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)	06 Oct 2020 13:06:13
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)	30 Sep 2020 16:30:44
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 'unknown subject tested positive again after 28 days follow up ' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	29 Sep 2020 15:38:34
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)	25 Sep 2020 12:30:37

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Outcome

Audit	User	Time (GMT)
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)	20 Sep 2020 22:35:24
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 'not recovered ' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	18 Sep 2020 12:18:12
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)	16 Sep 2020 14:52:12
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)	12 Sep 2020 17:32:02
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 'correct' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:06:33
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)	01 Sep 2020 14:29:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User entered empty.	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Narrative

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:03
User closed query 'PV Query: Please provide when the result of SARS-CoV-2 test performed on 04 Aug 2020 was available.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 22:08:56
Query 'PV Query: Please provide when the result of SARS-CoV-2 test performed on 04 Aug 2020 was available.' answered with 'positive' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	21 Oct 2020 21:00:26
User opened query 'PV Query: Please provide when the result of SARS-CoV-2 test performed on 04 Aug 2020 was available.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 13:06:32
User closed query 'PV Query: Please provide the dates when the results of SARS-CoV-2 RT-PCR tests performed on 27 Jul 2020 and 04 Aug 2020 were available.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 16:30:47
Query 'PV Query: Please provide the dates when the results of SARS-CoV-2 RT-PCR tests performed on 27 Jul 2020 and 04 Aug 2020 were available.' answered with '2AUG2020' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	29 Sep 2020 15:38:49
User opened query 'PV Query: Please provide the dates when the results of SARS-CoV-2 RT-PCR tests performed on 27 Jul 2020 and 04 Aug 2020 were available.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 12:30:56
User closed query 'PV Query: Please provide the dates when the results of SARS-CoV-2 RT-PCR tests performed on 27 Jul 2020 and 04 Aug 2020 were available.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 22:35:36
User closed query 'PV Query: Please report the reason for the delay in reporting the event.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 22:35:33
Query 'PV Query: Please provide the dates when the results of SARS-CoV-2 RT-PCR tests performed on 27 Jul 2020 and 04 Aug 2020 were available.' answered with 'correct' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	18 Sep 2020 12:18:42
Query 'PV Query: Please report the reason for the delay in reporting the event.' answered with 'confirmed' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	18 Sep 2020 12:18:31

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Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the dates when the results of SARS-CoV-2 RT-PCR tests performed on 27 Jul 2020 and 04 Aug 2020 were available.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 14:53:22
User opened query 'PV Query: Please report the reason for the delay in reporting the event.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 14:53:00
User closed query 'PV Query: Please provide the date the SARS-CoV-2 test performed on 27 Jul resulted.' (Site from Safety).	(b) (4), (b) (6)	12 Sep 2020 17:36:52
User closed query 'PV Query: The source documents report test collection dates of both 27-Jul-2020 and 04-Aug-2020. Please clarify if the subject had two tests. If yes, please provide results for both.' (Site from Safety).	(b) (4), (b) (6)	12 Sep 2020 17:36:48
User closed query 'PV Query: Please report if the patient had any known contacts, exposures or other risk factors for positive covid 19 test.' (Site from Safety).	(b) (4), (b) (6)	12 Sep 2020 17:36:45
User closed query 'PV Query: Please report the reason for the delay in reporting the event.' (Site from Safety).	(b) (4), (b) (6)	12 Sep 2020 17:36:43
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)	12 Sep 2020 17:36:41
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Sep 2020 17:32:22
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Sep 2020 17:32:20

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Narrative

Audit	User	Time (GMT)
Query 'PV Query: The source documents report test collection dates of both 27-Jul-2020 and 04-Aug-2020. Please clarify if the subject had two tests. If yes, please provide results for both.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:06:58
Query 'PV Query: Please report if the patient had any known contacts, exposures or other risk factors for positive covid 19 test.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:06:55
Query 'PV Query: Please report the reason for the delay in reporting the event.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:06:51
Query 'PV Query: Please provide the date the SARS-CoV-2 test performed on 27 Jul resulted.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:06:48
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 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:06:44
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:06:40
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:06:37
User entered 'subject only taken Tylenol for headache. Subject don't have any medical history to add.' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 18:04:41
User opened query 'PV Query: The source documents report test collection dates of both 27-Jul-2020 and 04-Aug-2020. Please clarify if the subject had two tests. If yes, please provide results for both.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 14:31:02

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Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please report if the patient had any known contacts, exposures or other risk factors for positive covid 19 test.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 14:30:31
User opened query 'PV Query: Please report the reason for the delay in reporting the event.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 14:30:20
User opened query 'PV Query: Please provide the date the SARS-CoV-2 test performed on 27 Jul resulted.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 14:30:07
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)	01 Sep 2020 14:29:46
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 14:28:29
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 14:28:18
User entered empty.	Shanice Bennett (b) (4) (b) (4)	04 Aug 2020 19:02:46

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Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 01:01:22
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Amendment Manager: User entered '1'	System	21 Aug 2020 01:01:22
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

US3022012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:53

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:19

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:09:57
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:42:28
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:51:20

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:31:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:31:52
Data point term sent to Coder	System	07 Dec 2020 18:31:05
Coding entries removed.	(b) (4), (b) (6)	07 Dec 2020 18:31:02
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 19:00:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 19:00:42
Data point term sent to Coder	System	22 Sep 2020 19:00:06
Coding entries removed.	Shanice Bennett (b) (4) (b) (4)	22 Sep 2020 18:59:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:53:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:53:48
Data point term sent to Coder	System	10 Sep 2020 17:52:44
User entered 'Tylenol'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

FDA-CBER-2022-1614-0019057

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Indication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:31:02
User entered 'Possible COVID-19' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 18:31:02
User closed query 'Please confirm/clarify if this is a symptom of Covid. If so please update indication to Covid-19 AE indication or clarify. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:01:14
Query 'Please confirm/clarify if this is a symptom of Covid. If so please update indication to Covid-19 AE indication or clarify. ' answered with 'UPDATED' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 14:43:22
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User opened query 'Please confirm/clarify if this is a symptom of Covid. If so please update indication to Covid-19 AE indication or clarify. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:44:12
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the Headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Headache did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:43:20

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the Headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Headache did not meet the AE reporting criteria.' answered with 'did not meet reporting AE criteria' (Site from DM).	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 18:07:38
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the Headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Headache did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:08:42
User closed query 'Per CDM: Diary Dose Temperature day form indicates subject also had a fever from 28 July 2020 until 1 August 2020. Please confirm/clarify if additional information should be added to Concomitant Medication form and reconcile appropriately. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 11:50:17
Query 'Per CDM: Diary Dose Temperature day form indicates subject also had a fever from 28 July 2020 until 1 August 2020. Please confirm/clarify if additional information should be added to Concomitant Medication form and reconcile appropriately. ' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	22 Sep 2020 18:59:57
User entered 'HEADACHE/FEVER' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	22 Sep 2020 18:59:52

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Indication

Audit	User	Time (GMT)
User opened query 'Per CDM: Diary Dose Temperature day form indicates subject also had a fever from 28 July 2020 until 1 August 2020. Please confirm/clarify if additional information should be added to Concomitant Medication form and reconcile appropriately. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 17:02:29
User entered 'Headache'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User entered '500'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User entered 'mg (mg)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User entered 'once daily (QD)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User entered '28 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User entered '01 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:44:56
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:14:08
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:33:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:33:13
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:54:57
User entered 'No (N)' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 18:07:34
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 17:52:15

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US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:52:15

US3022012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:52:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:52:15

FDA-CBER-2022-1614-0019076

US3022012

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:54:53

Were any concomitant procedures performed?

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'No (N)'	(b) (4), (b) (6)	25 Oct 2020 22:57:24

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered 'Visit 2 Day 29 (VISIT2)'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Visit Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '1'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Demographics

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Enrollment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Inclusion/Exclusion Criteria Summary

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Inclusion/Exclusion Criteria

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53

Medical History Summary

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Medical History

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Vital Signs

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '1'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Vital Signs - Dosing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '1'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Physical Examination

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53

Central Laboratory - Nasopharyngeal Swab

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '1'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Childbearing Potential

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53

Pregnancy Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Randomization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Exposure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '1'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

Immunogenicity Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '1'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

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US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Saliva Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
COVID Diagnostic Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Symptom Log

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
COVID-19 Severity Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

COVID-19 Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53

Risk of Exposure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Safety Call

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Dosing Discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

End of Study / Study Discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

All

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Date of missed or out of window visit or assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '31 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Inclusion criteria not met/Exclusion criteria met

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Study Treatment not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Missed Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '1'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

Missed Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Visit performed out of window

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Assessment performed out of window

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Scheduled clinical visit performed as home visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Clinical site closed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Travel restrictions

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Quarantine due to COVID-19

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '1'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Possible exposure to COVID-19

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Exposure to COVID-19

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53

Presumption / confirmed COVID-19

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012
Folder: COVID-19 Impact (1)
Form: COVID-19 Impact (1)
Generated On: 11 Aug 2021 21:54:53
Symptoms of COVID-19

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Sponsor hold due to COVID-19

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

US3022012

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 21:54:53

Participant decision

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:27:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Oct 2020 12:15:28

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:55:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '02 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	29 Sep 2020 15:39:18

FDA-CBER-2022-1614-0019125

US3022012

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:54:53

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:55:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Per CDM: As per the CCG page no. 43(V2.0), Due to SARS CoV-2 can be selected as primary reason from list. Please review, reconcile and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 14:15:55
Query 'Per CDM: As per the CCG page no. 43(V2.0), Due to SARS CoV-2 can be selected as primary reason from list. Please review, reconcile and update accordingly. Thank you.' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 20:22:41
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 20:22:37
User opened query 'Per CDM: As per the CCG page no. 43(V2.0), Due to SARS CoV-2 can be selected as primary reason from list. Please review, reconcile and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:45:34
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	29 Sep 2020 15:41:11
User entered 'Due to SARS-COV-2 (COVID)'	Shanice Bennett (b) (4) (b) (4)	29 Sep 2020 15:39:18

US3022012

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:54:53

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:55:05
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 20:23:08
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 20:23:08
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 20:22:37
User entered 'positive COVID-19' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	29 Sep 2020 15:41:11
User entered empty.	Shanice Bennett (b) (4) (b) (4)	29 Sep 2020 15:39:18

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'USA-US051-2020-MRNA-1273-P301000002'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019131

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019134

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019136

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019137

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered ' (b) (6) '	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019138

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6) '	System	28 Aug 2020 17:33:52

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019140

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:30:08
User entered 'US' (non-conformant).	System	28 Aug 2020 17:36:39

FDA-CBER-2022-1614-0019142

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '6'	System	22 Oct 2020 22:09:57
User entered '5'	System	30 Sep 2020 16:31:10
User entered '4'	System	21 Sep 2020 11:36:34
User entered '3'	System	15 Sep 2020 12:52:10
User entered '2'	System	12 Sep 2020 17:30:20
User entered '1'	System	28 Aug 2020 17:36:39

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'USA-US051-2020-MRNA-1273-P301000002'	System	28 Aug 2020 17:33:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019145

US3022012

Folder: SAE USA-US051-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:54:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019150

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019152

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019155

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019157

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:30:08
User entered 'US' (non-conformant).	System	28 Aug 2020 17:36:39

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '6'	System	22 Oct 2020 22:09:57
User entered '5'	System	30 Sep 2020 16:31:10
User entered '4'	System	21 Sep 2020 11:36:34
User entered '3'	System	15 Sep 2020 12:52:10
User entered '2'	System	12 Sep 2020 17:30:20
User entered '1'	System	28 Aug 2020 17:36:39

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form (1)
Generated On: 11 Aug 2021 21:54:53
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
User entered '28/Aug/2020 13:36'	System	28 Aug 2020 17:36:39

US3022012

Folder: SAE USA-US051-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:54:53

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.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:30:08
User entered '1'	(b) (4), (b) (6)	28 Aug 2020 17:36:39

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'USA-US051-2020-MRNA-1273-P301000002'	System	28 Aug 2020 17:33:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019163

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019167

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019170

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019174

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019175

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:30:08
User entered 'US' (non-conformant).	System	28 Aug 2020 17:36:39

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '6'	System	22 Oct 2020 22:09:57
User entered '5'	System	30 Sep 2020 16:31:10
User entered '4'	System	21 Sep 2020 11:36:34
User entered '3'	System	15 Sep 2020 12:52:10
User entered '2'	System	12 Sep 2020 17:30:20
User entered '1'	System	28 Aug 2020 17:36:39

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form (2)
Generated On: 11 Aug 2021 21:54:53
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
User entered '12/Sep/2020 13:30'	System	12 Sep 2020 17:30:20

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.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
User entered '1'	(b) (4), (b) (6)	12 Sep 2020 17:30:20

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'USA-US051-2020-MRNA-1273-P301000002'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019182

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019184

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019190

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019191

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

PRODUCTION RELEASE (v12.003
EAB) (1725)

2553 of 2612

FDA-CBER-2022-1614-0019192

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:30:08
User entered 'US' (non-conformant).	System	28 Aug 2020 17:36:39

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '6'	System	22 Oct 2020 22:09:57
User entered '5'	System	30 Sep 2020 16:31:10
User entered '4'	System	21 Sep 2020 11:36:34
User entered '3'	System	15 Sep 2020 12:52:10
User entered '2'	System	12 Sep 2020 17:30:20
User entered '1'	System	28 Aug 2020 17:36:39

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3022012

Folder: SAE USA-US051-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:54:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
User entered '15/Sep/2020 08:52'	System	15 Sep 2020 12:52:10

US3022012

Folder: SAE USA-US051-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:54:53

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.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:36:24
User entered '1'	(b) (4), (b) (6)	15 Sep 2020 12:52:10

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'USA-US051-2020-MRNA-1273-P301000002'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019204

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019205

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019209

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019210

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:30:08
User entered 'US' (non-conformant).	System	28 Aug 2020 17:36:39

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '6'	System	22 Oct 2020 22:09:57
User entered '5'	System	30 Sep 2020 16:31:10
User entered '4'	System	21 Sep 2020 11:36:34
User entered '3'	System	15 Sep 2020 12:52:10
User entered '2'	System	12 Sep 2020 17:30:20
User entered '1'	System	28 Aug 2020 17:36:39

US3022012

Folder: SAE USA-US051-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:54:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
User entered '21/Sep/2020 07:36'	System	21 Sep 2020 11:36:34

US3022012

Folder: SAE USA-US051-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:54:53

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.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 16:30:59
User entered '1'	(b) (4), (b) (6)	21 Sep 2020 11:36:34

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'USA-US051-2020-MRNA-1273-P301000002'	System	28 Aug 2020 17:33:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019217

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019219

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019221

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019222

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019224

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019226

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019227

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019228

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019229

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:30:08
User entered 'US' (non-conformant).	System	28 Aug 2020 17:36:39

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '6'	System	22 Oct 2020 22:09:57
User entered '5'	System	30 Sep 2020 16:31:10
User entered '4'	System	21 Sep 2020 11:36:34
User entered '3'	System	15 Sep 2020 12:52:10
User entered '2'	System	12 Sep 2020 17:30:20
User entered '1'	System	28 Aug 2020 17:36:39

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form (5)
Generated On: 11 Aug 2021 21:54:53
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
User entered '30/Sep/2020 16:31'	System	30 Sep 2020 16:31:10

US3022012

Folder: SAE USA-US051-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 21:54:53

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.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 16:48:42
User entered '1'	(b) (4), (b) (6)	30 Sep 2020 16:31:10

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'USA-US051-2020-MRNA-1273-P301000002'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

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US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019240

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered 'No (N)'	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019241

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019244

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

FDA-CBER-2022-1614-0019245

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 12:51:56
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:39:48
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:39:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:36:32
User entered (b) (6)	System	28 Aug 2020 17:33:52

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:35:32
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 17:30:08
User entered 'US' (non-conformant).	System	28 Aug 2020 17:36:39

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 21:54:53
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
User entered '6'	System	22 Oct 2020 22:09:57
User entered '5'	System	30 Sep 2020 16:31:10
User entered '4'	System	21 Sep 2020 11:36:34
User entered '3'	System	15 Sep 2020 12:52:10
User entered '2'	System	12 Sep 2020 17:30:20
User entered '1'	System	28 Aug 2020 17:36:39

US3022012
Folder: SAE USA-US051-2020-MRNA-1273-P301000002
Form: Safety Report Form (6)
Generated On: 11 Aug 2021 21:54:53
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
User entered '22/Oct/2020 18:09'	System	22 Oct 2020 22:09:57

US3022012

Folder: SAE USA-US051-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 11 Aug 2021 21:54:53

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.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:37:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:35:32
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 22:09:57